and the amount of funding contributed by the grantee to project cost. The initial Notice of Federal Financial Assistance Awarded also specifies the total project period for which Federal support is contemplated.

Special Considerations for Funding

In FY 1980, special consideration will be given project proposals in which the population to be served consists exclusively or predominantly of severely disabled Hispanic people.

Criteria for Review and Evaluation of Grant Applications

All new and competing continuation applications received on a timely basis and conforming with the guidelines in this announcement will be reviewed by qualified experts. Applications are rated in accordance with the following numerical scale of 0 to 4: Not Acceptable—0, Poor—1, Acceptable—2, Above Average—3, and Outstanding—4.

The specific criteria against which applications will be evaluated are listed below:

1. Project objectives are identical with or are capable of achieving program objectives as defined in this announcement.
2. Project activities or tasks are capable of achieving project objectives.
3. Estimated cost to the Government is reasonable in relation to anticipated project results.
4. Budget items are appropriate in relation to project activities.
5. Adequate facilities are available to the applicant to carry out the project.
6. Project personnel, actual or proposed, are, or will be, well trained and qualified.
7. Staffing levels are adequate to carry out the project.
8. Project contains an adequate evaluation component.
9. Project provides for adequate liaison with the State rehabilitation agency and community groups to ensure client referrals, outreach and utilization of project results.
10. Project demonstrates the potential for the project to be continued after termination of Federal support.
11. Project demonstrates the potential for project results to be effectively utilized after termination of support.

Closing Date for Receipt of Applications

New and competing continuation applications must be received by March 14, 1980. Applications will be judged on time if:

a. The application was sent by mail not later than the date specified above as evidenced by the U.S. Postal Service postmark or the original receipt from the U.S. Postal Service, or

b. The application is hand-delivered to the office designated for the submission of the application. Hand-delivered applications will be accepted no later than the close of business on the date specified above.

(Catalog of Federal Domestic Assistance Number 13.626, Rehabilitation Services and Facilities Special Projects.)

Dated: December 28, 1979.

Robert R. Humphreys,

Commissioner of Rehabilitation Services.

Approved: January 11, 1980.

Manuel Carballo,

Assistant Secretary for Human Development Services.

[FR Doc. 80-1462 Filed 1-16-80; 8:45 am]

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federal register

Thursday
January 17, 1980

Part IV

Department of Health, Education, and Welfare

Office of Human Development Services

Child Abuse and Neglect Grant Program Priorities, Fiscal Year 1980; Research, Demonstration and Service Improvement Grants

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of Human Development Services

Child Abuse and Neglect Grant Program Priorities, Fiscal Year 1980; Research, Demonstration and Service Improvement Grants

AGENCY: Office of Human Development Services, Department of Health, Education, and Welfare.

ACTION: Notice of proposed Fiscal Year 1980 Child Abuse and Neglect Research, Demonstration and Service Improvement priorities.

SUMMARY: This notice states the research, demonstration and service improvement (R, D, & S) priorities that the National Center on Child Abuse and Neglect/Children's Bureau proposes to initiate on Fiscal Year 1980, under the Child Abuse Prevention and Treatment Act (Pub. L. 93–247, as amended). This notice is being published in order that the final R, D, & S priorities may incorporate and reflect the expertise of individuals knowledgeable in the field.

DATE: In order to be considered, comments must be received no later than March 17, 1980. Comments on these proposed priorities or suggestions for other priorities are invited. *No proposals, concept papers or other forms of application should be submitted at this time.*

ADDRESS: Comments should be sent to: Associate Chief, Children's Bureau/ACYF, P.O. Box 1182, Washington, D.C. 20013.

FOR FURTHER INFORMATION CONTACT: National Center on Child Abuse and Neglect, Children's Bureau/ACYF, P.O. Box 1182, Washington, D.C. 20013. (202) 755–0587.

SUPPLEMENTARY INFORMATION: In 1978, the Child Abuse Prevention and Treatment Act (Pub. L. 93–247) was amended by Pub. L. 95–266. Included in the amendments was a section specifically authorizing appropriations up to $4 million in Fiscal Year 1980 and Fiscal Year 1981 for the purpose of supporting research, demonstration and service improvement grants, grants to States and training and technical assistance projects specifically focused on the prevention and treatment of *child sexual abuse.* Congress appropriated the full $4 million for Fiscal Year 1980. This statement announces the proposed R, D, & S priorities to be funded in Fiscal Year 1980. Public review of these proposed priorities is being sought, as required by Pub. L. 93–247, as amended, in order to draw upon the experience and most advanced thinking of persons in the field and to maximize the potential benefits of the research, demonstration and service program for the prevention and treatment of child sexual abuse.

The National Center on Child Abuse and Neglect/Children's Bureau (NCCAN/CB) conducts activities designed to assist and enhance national, state, community and citizen efforts to prevent, identify and treat child abuse and neglect. The activities include: conducting research and demonstrations; supporting service improvement projects; gathering, analyzing and disseminating information through a clearinghouse; providing grants to eligible States for strenthening and improving their child abuse and neglect prevention and treatment programs and coordinating Federal activities in child abuse and neglect through the Federal Advisory Board on Child Abuse and Neglect. Thus, there are many activities other than the research, demonstration and service program proposed in this notice which require staff and financial support by NCCAN/CB.

FY 1980 is the first year in which an appropriation is available under the amendments to Pub. L. 93–247 for the special child sexual abuse prevention and treatment program. These funds must be allocated in keeping with the requirements outlined in Section 5 of the Act for the total child abuse and neglect program. Therefore, 30% or $1.2 million must be used to supplement State grants authorized by Section 4(b). No less than 50% or $2 million must be used for support of grants and contracts to non-profit organizations and public agencies for research, demonstration and services. In addition, the amendments to Section 5 require that no more than 10% or $400,000 be used to support research and that no less than 3 centers for treatment and training related to the prevention and treatment of child sexual abuse be established.

Though appropriations were not available to support the child sexual abuse provisions of the 1978 amendments in previous fiscal years, the National Center on Child Abuse and Neglect/Children's Bureau (NCCAN/CB) supported some demonstration and developmental activities in this area under its general authority. Thus, four demonstration projects on the clinical treatment of child sexual abuse were awarded for three and one-half year project periods beginning in September, 1978. One project was supported beginning in FY 1978 for a one year period to develop training materials. In Fy 1979, one project was funded to serve as a pilot for the treatment and training centers required by the amendments, under the title of Child Sexual Abuse Treatment-Training Institute.

In developing this plan to implement the amendments relating to child sexual abuse, NCCAN/CB has held and attended numerous meetings of its own funded child sexual abuse projects and related projects supported by the Department of Justice, Child Protective Service officials from the States, and interested professionals from across the country. Participants have included representatives from the fields of criminal justice, law enforcement, social services, psychology, psychiatry and education.

Recommendations from these representatives of service delivery systems related to intervention and treatment of child sexual abuse have been incorporated in the preparation of this plan. General guidance from the field includes an urgent concern that NCCAN/CB act as quickly as possible to implement this program, since only two years of authorization remain of the four year period for which the legislation provided authority. Both public and private providers of services and representatives of the criminal justice system underscore the frightening challenge caused by the increase in reports of intrafamily child sexual abuse, which amounts to a nearly 100% increase between 1976 and 1978 alone (The American Humane, 1978). The field also clearly demonstrates the continuing debate between social service/treatment approaches to child sexual abuse intervention and follow-up for victims and their families and law enforcement/criminal justice approaches. Finally, the field supports the position indicated by the legislative requirements; a priority need is for better trained professionals to know how to intervene and how to treat cases of child sexual abuse.

To meet the requirements of the legislation and be responsive to the needs of the field, NCCAN/CB proposes to allocate the $4 million available for child sexual abuse prevention and treatment activities as follows:

State Grants.—Supplements to grants to states and jurisdictions eligible under the requirements of Section 4(b) of the Act amounting to 30% (or $1.2 million) of the total earmarked appropriation are required by the Act. Announcement of this grant program is being published separately from this statement of proposed priorities.

Research: NCCAN/CB proposes to award grants for research which address: (1) the impacts of alternative interventions in known or suspected cases of child sexual abuse; (2) the exploitation of children in pornography;

(3) and the causes and effects of intrafamily child sexual abuse. A total of 10% of the earmarked appropriation (or $400,000) will be allocated for purposes of research.

Demonstration: NCCAN/CB proposes to award grants to test and demonstrate an approach to the prevention of child sexual abuse which involves the education of school-age children. In fulfillment of the requirements of the Act, as amended, NCCAN/CB proposes to award grants to demonstrate programs for training professionals in intervention and treatment of child sexual abuse. The Act, as amended, calls for a minimum of three centers for the treatment and training of child sexual abuse to be established. In order to provide for nationwide access to this treatment-training program, NCCAN/CB proposes to support a total of five such centers, including the one already established in Fiscal Year 1979 as a pilot project. A total of $1.4 million will be allocated for purposes of supporting demonstration programs. A project description for the treatment-training projects is not included in this statement, because it was previously published for public comment in the **Federal Register** on May 23, 1979. A Program Announcement will be published, soliciting applications for this program, in February, 1980.

Service Improvement: NCCAN/CB proposes to award grants to public and private nonprofit agencies for the purposes of installing specialized intervention and/or treatment program components and developing interagency resource development capabilities in responding to and treating known and suspected cases of child sexual abuse. A total of $700,000 will be allocated for the support of service improvement grants.

In addition to these proposed R, D, & S proposed priorities, NCCAN/CB will allocate $300,000 to support needed technical assistance and training inititatives which will be implemented in Fiscal Year 1980. These initiatives are not included as project descriptions in this statement of proposed priorities.

NCCAN/CB specifically requests the comments, suggestions and guidance of knowledgeable and concerned professionals in the field in refining the research issues and questions noted in the proposed project descriptions for research projects on the impacts of alternative interventions, the use of children in pornography and intrafamily child sexual abuse.

Specific comments and suggestions are solicited concerning each of the priorities described below. *No proposals, concept papers or other forms of application should be submitted at this time.* Any such submissions will be discarded. In order to maintain a procedure fair to everyone, applications will be accepted only in response to the final Program Announcements to be published at a later date(s) in the **Federal Register.**

No acknowledgment will be made of the comments received, but all of them will be considered in preparing the final Program Announcements of the child sexual abuse research, demonstration and service improvement programs. In addition, all persons commenting on the proposed priorities will be placed on the mailing list to receive the final Program Announcements and application materials. It is anticipated that the Program Announcements will be published in the Spring of 1980 subject to Departmental approvals.

Proposed Project Descriptions

(1) *Project Title:* **Research on Child Sexual Abuse: Impacts of Alternative Interventions**

Number Cost and Duration: One grant will be awarded for a total project period of two years. The initial award and the subsequent noncompeting continuation award will be funded at a level of approximately $250,000 each.

Importance and Purpose: Over the past few years intrafamily child sexual abuse has become recognized as a significant social problem. In response to this recognition in numerous communities across the nation new programs have been developed or existing child abuse and neglect programs have been modified to meet the needs of child victims and their families. Meanwhile the most typical response to the discovery of intrafamily child sexual abuse has been one which engages the law enforcement and criminal justice systems and only peripherally incorporates child protective services or child abuse and neglect treatment resources. In fact, no universally accepted approach to the provision of services has yet emerged. Even within the two basic intervention approaches, there are a number of variations and combinations in some communities. By examining the differences, in terms of their impacts on the children and the families involved, it will be possible to establish future policy and program directions for addressing this social problem.

Methodology: This research effort will undertake a comparative study of alternative intervention approaches. The methodology for such research must include:

(a) Selection of programs to be included in data collection and analysis

(b) Selection of sample populations of clients who have received services within these programs for data collection

(c) Methodology for selecting a control group (using retrospective data) which received no intervention and/or a comparison control group which was exposed to criminal prosecution without the benefit of other therapeutic intervention.

(d) Development of specific hypotheses regarding the possible impacts on child victims and families of alternative intervention approaches

(e) Design (in collaboration with the selected programs) of data collection plans and data analysis plans

(f) Collection of specified data

(g) Analysis of collected data, including examination of specific hypotheses

(h) Development of conclusions and recommendations.

Expected Findings: The programs and client families to be studied in this research will not constitute a neat experimental design. However, it should be possible to examine, in a single study, comparisons between the basic approaches to intervention and to consider the variations within and the combinations of those approaches in terms of their efforts on the child victims and their families. As a result of this research, it should be possible to make considerable progress toward answering the following type of questions:

(a) How does the provision of social services simultaneously with criminal prosecution of the perpetrator affect safety for the child, family stability, cooperation with treatment, motivation change, etc., compared to the provision of social services without prosecution or vice versa?

(b) How do the results of the following kinds of intervention strategies compare: (1) All family members remain in the household during a period of psychotherapeutic treatment; (2) The perpetrator lives apart from the household during a period of psychotherapeutic treatment; (3) The abused child lives apart from the household during a period of treatment.

(c) What are the effects and/or costs to the family and its individual members of various types of intervention?

(d) What are the costs to society of various types of intervention and/or no intervention at all?

Utilization: Existing and future programs for responding to reports of intrafamily child sexual abuse can be improved in light of new knowledge about the effects of alternative interventions. That is, to the extent that this study can answer key policy and

program questions, community programs can be designed or modified to better serve involved families.

(2) *Project Title:* **Research on the Use of Children in Pornography**

Number, Cost and Duration: One grant will be awarded for a total project period of two years. The initial award and the subsequent noncompeting continuation award will be approximately $50,000 each year.

Importance and Purpose: the 1978 amendments to the Child Abuse Prevention and Treatment Act expanded the definition of child abuse and neglect to include the sexual exploitation of children. Among the kinds of sexual exploitation included in the definition is the use of children in pornography. While there are no reliable data on the magnitude of this problem, it is clear from anecdoctal evidence and surveys of pornographic periodic literature and films, as well as from testimony before Congressional hearings, that the problem is significant in its dimensions, especially in certain metropolitan areas of the country. To begin to address appropriate and effective interventions into this problem, better understanding is necessary. The purpose of this research project is to increase knowledge about the nature and scope of the use of children in pornography and to begin to assess its etiology and its relationships to other forms of child maltreatment.

Methodology: This grant will constitute a "field initiated" research project, rather than one which must conform to a predetermined design or structure. Applications should conform to basic research guidelines (regarding selections of sample populations, data collection and analysis, for example) and must be aimed at answering/exploring questions which are central to the problem of understanding the involvement of children in the pornographic industry. Given the questions selected by applicants to address, each application must suggest an appropriate methodology.

Expected Findings: This research effort is viewed as a first step toward increasing recognition and understanding of the problem of the use of children in pornography. The specific questions that will be answered or explored will depend upon the research application which is chosen for award. Although the competitive process will permit the submission of a wide range of proposals, the following types of questions are examples of the types of issues which could be investigated:

(a) What are the characteristics of the children (such as personal, environmental, demographic, etc.) who are used in pornography?

(b) What are the characteristics of the family backgrounds of the children (including former incidence of child maltreatment within the home)?

(c) What are the significant relationships ("significant others") of children who are being used in pornography, how are they related to them and why do children become involved in pornography?

(4) How is child pornography related to other social problems such as child prostitution substance abuse incest, delinquency, and running away?

The entire focus of this research will be the child "victim" and his or her former and present relationships. Research proposals which are focused on the "consumers" of child pornography will be specifically excluded from consideration.

Utilization: The findings from this research will contribute to an urgently needed data base concerning the nature of child pornography and the types of individuals and circumstances associated with commercial sexual exploitation of children. Such basic information is necessary in order to design and improve interventions and treatment for the child victims of the pornographic industry, and to prevent the exploitation of children in the future.

(3) *Project Title:* **Field Initiated Research on Intrafamily Child Sexual Abuse**

Number, Cost and Duration: Approximately one to two grants will be awarded for a total project period of three years depending upon the availability of funds. The initial award and the subsequent noncompeting continuation awards will be approximately $50,000 each.

Importance and Purpose: Previous research conducted under the auspices of NCCAN/CB has been directed at either evaluating specific programs (such as the national evaluation of the Clinical Treatment Demonstration Program, now in progress) or at specified issues and research questions (such as the proposed research on the use of children in pornography and on the impacts on alternative interventions). By definition, this approach limits the areas of investigation as well as the initiative and acquired expertise of researchers whose work in this area has increasingly emerged in the last five years. While directed research continues to be necessary in order to meet the Congressional mandate and fill important information gaps, social scientists, whose expertise and knowledge base already exceeds the preliminary work conducted under Government auspices, need to be supported in pursuing their self-defined research priorities in the area of child sexual abuse. The purpose of inviting research proposals on topics within this subject area is to support the most current thinking and creative approaches of researchers in this field and to expand the common knowledge and findings already available to them.

Methodolgy: These proposed research projects will not be required to conform to a predetermined design, structure or sets of hypotheses. Applications will be solicited which conform to basic research guidelines regarding selection of sample populations and data collection and analyses, through the use of rigorous social science methodologies. Research topics must address some aspect of *intrafamily child sexual abuse* which may be defined to include extended family and/or parental figures or other "significant others" in a child's life and may constitute either basic or applied research in service settings (including program assessment and evaluation). Each application must propose an appropriate and feasible methodology for the research questions or issues addressed. If the design includes the use of data gathered from an existing program or client population, it must include assurances from the cognizant program officials of the accessibility and availability of such data under conditions which safeguard individual rights of privacy and confidentiality.

Expected Findings: This research is expected to generate new knowledge and improve understanding of the most problematic, and possibly the most prevalent, form of child sexual abuse: incest and related forms of intrafamily child sexual abuse. The specific questions to be answered and the anticipated findings of the study(ies) will depend upon the particular research application(s) funded. Aspects of intrafamily child sexual abuse could include nature, causes and effects of sexual maltreatment or intervention/treatment. Although the competitive process will permit the submission of a wide range of subject areas, the following are examples of the type of research questions which could be addressed:

(a) Child sexual abuse as a factor of other current or past family dysfunction such as: behavioral problems in children or adults, psychological and sexual adjustment problems, substance abuse, running away, spouse abuse and delinquency.

(b) Short- and long-term follow-up on the effects on victims of disclosed and undisclosed incest.

(c) Extent, nature and treatment of the sexual abuse of boys.

(d) The etiology of child sexual abuse and the treatment of perpetrators.

(e) The sources of trauma and sources of resilience to trauma in victims of child sexual abuse.

(f) Effects of intrafamily child sexual abuse on siblings of the victims; the nature and treatment of sexual abuse by siblings.

(g) Child sexual abuse in stepfather-families.

(h) The extent, nature and effects of venereal disease and/or pregnancy as a result of incest.

(i) Patterns of communication/degree of dysfunction in the family systems of incest families.

(j) The effects of various factors associated with incest (age of victim, degree of coercion involved, violence involved, extent of abuse, secrecy, victim's passivity or fear, familial relationship to offender, type of intervention).

Utilization: The findings will be disseminated to the field to assist researchers in identifying avenues in need of further study, contribute to the improvement of current programs, and increase understanding of the problem and its causes, prevention and treatment.

(4) *Project Title:* **Demonstration of Prevention of Child Sexual Abuse Through the Education of School Age Children**

Number, Cost and Duration: Approximately three to four grants will be awarded for a total project period of two years, and one grant will be awarded for a total project period of three years. The initial award and the subsequent noncompeting continuation awards for the three smaller grants will be approximately $30,000 to $50,000 each. The initial award and the subsequent noncompeting continuation award for the one larger grant will be approximately $80,000 to $100,000 each year.

Importance and Purpose: Prevention of child sexual abuse, particularly incest, poses a challenge in a society which holds the privacy of family life as a principal value. Yet, the increase in reported incidents of child sexual abuse (which most agree are only a small proportion of the actual number) makes that challenge one which cannot be ignored. One approach to the prevention of child sexual abuse involves increasing the awareness of children to the problem. Surveys have shown that, while most children generally know not to accept candy or rides from strangers, they often do not know why they have been warned to be careful or that they are similarly vulnerable to people whom they know. (Studies have repeatedly shown that a major proportion of reported cases of child sexual abuse involve perpetrators who are known and trusted by their child victims.) Similarly, children are ofter embarrassed or fearful to talk to anyone about negative sexual experiences, and are usually not aware that others have had the same experiences or that there are any resources to help them to deal with the problem.

Such findings point to the need to provide better education for young children concerning the existence of sexual abuse, and equipping them with knowledge concerning early warning signs, their own rights to physical privacy, and techniques to avoid or resist sexual exploitation by adults. A few programs around the country have begun this effort by attempting to sensitize children to acceptable and unacceptable forms of physical interactions with adults and to provide them with linkages to service resources when they feel that their personal physical privacy is being violated.

The purpose of this set of demonstration projects will be to build upon these small local beginnings to further test and demonstrate the use of education programs for school-age children as a means of preventing child sexual abuse.

Methodology: Approximately five grants will be awarded (three to four in one category and one in the other) for two basic levels of activity relating to the prevention of child sexual abuse: (1) Three to four small projects demonstrating various approaches to preventing child sexual abuse using educational models for school age children; and (2) One larger collaborative prevention project whose purpose will be: to develop and test additional new and innovative techniques for prevention of child sexual abuse, to provide orientation and supporting information for implementing the smaller prevention projects, and to conduct collaborative research on the processes and effects of the educational prevention projects.

Prevention Through Education Projects. Approximately three or four grants will be awarded to support school systems, social service agencies, or any other nonprofit agencies which can certify access to populations of school-age children, for the purpose of developing and delivering curricula aimed at equipping children to resist sexual exploitation. Applications should include a design and methodology for implementing an educational prevention program as well as an outline for the basic curriculum to be utilized.

Collaborative Prevention Resource Project. One grant will be awarded to an organization or agency which has already pilot tested a program similar to the one proposed above. The project will be funded for a period of three years, depending on the availability of funds, in order to allow for a follow-up evaluation of the total program. The purpose of the project will be to carry out the following objectives: (1) To refine and expand the educational program to include additional curiculum content on forms of child sexual abuse which may not have been previously addressed and to demonstrate the expanded curriculum's use with additional child populations (such as adolescents); (2) To provide orientation and supporting information, based on its previous experience, to the three or four similar demonstration prevention projects in oder to assist them in start-up and implementation of their programs; (3) To disseminate information to communities desiring to establish child sexual abuse prevention programs; and (4) To conduct a collaborative research, in conjunction with the smaller prevention projects, based on its own and their project experience, to assess the effectiveness of curricula the relative receptivity of various age groups, the variations of project results as related to project auspice and geographic location, and the effects of systemic barriers to institutionalizing prevention programs for school-age children.

The collaborative resource project will meet together with the prevention through education projects to provide assistance with start-up, share skills, approaches and curriculum materials, and design evaluation methodologies at least once each year. The collaborative project will be responsible for hosting the meetings, setting agenda together with NCCAN/CB Project Officers, providing inservice training for other projects staff and technical assistance on issues of implementation.

Expected Findings: It would not be realistic to expect to be able to document the ultimate impacts of this approach to prevention of child sexual abuse within the limited time period and budget available at this time. Such an evaluation would require a longitudinal study which would go well beyond the period of authorization for this program. However, it should be possible to assess problems of implementation, community

acceptance, and short-term effects for children who are served by the projects. If past experience by some of the existing educational programs is any indication, a significant number of actual cases will be discovered through these projects, and the prevention of further sexual abuse through timely intervention will be documented.

Utilization: Findings and developed curricula will be disseminated broadly to educational systems (through the NCCAN/CB National Resource Center for Educators, sponsored by the Education Commission of the States), to social service agencies, and to child advocacy organizations. The purpose of such dissemination will be to support other localities in implementing similar prevention/education programs.

(5) *Project Title:*

Service Improvement Projects for the Management and Treatment of Child Sexual Abuse Cases

Number, Cost and Duration: Approximately ten grants will be awarded (for two different types of service improvement projects) for a total project period of three years each, depending upon the availability of funds. The initial award and subsequent noncompeting continuation awards for half of the service improvement grants will be approximately $50,000. The initial award and subsequent noncompeting continuation awards for the other half of these grants will be approximately $50,000 to $80,000 each.

Importance and Purpose: Most child protective agencies report problems of large caseloads and too few resources for adequate diagnosis and treatment. At the same time, they, like other community intervention and treatment agencies, are seeing a steadily increasing number of child sexual abuse cases. Previously funded child abuse demonstration projects have documented the fact that child sexual abuse cases pose particularly difficult investigation and treatment problems which require specialized approaches, followed by intensive supervision and monitoring. Few community agencies are able to meet that need due to either a lack of resources or lack of opportunity to implement specialized programs. In addition, a lack of coordination between the many community agencies which become involved in cases of child sexual abuse makes case management difficult and adds to the confusion and trauma being experienced by these families.

The purpose of these service improvement projects is: (1) To support communities in their efforts to substantially improve the delivery of services to victims of child sexual abuse and their families through installation of new or modified program components in existing public or private service agencies; and (2) To support community agencies having responsibilities for handling child sexual abuse cases (particularly the criminal justice and social service systems) in their efforts to work together in a team approach to improve coordination of services, define roles, responsibilities and available treatment alternatives, increase the community resources needed to deal with the problem, and reduce the trauma experienced by victims and their families.

Methodology: Grants will be awarded in two basic categories of intervention and/or treatment projects: (1) To install specialized child sexual abuse intervention and/or treatment program components in public or private agencies with existing child protective service and treatment roles; and (2) To support tri-service community resource team projects which will enhance coordination among the cognizent agencies responsible for handling cases of child sexual abuse, and improve intervention and treatment services in at least three community agencies.

The *specialized service component projects* will focus on the development of special units or staff components which will have exclusive responsibility for handling cases of child sexual abuse and for upgrading the quality of services available to victims and their families. Methods for improving services for child sexual abuse could involve: specialized intake and investigation procedures, increased availability of outreach, treatment, and supportive services, development of specialized out-of-home placement facilities for victims, establishment of self-help components, group therapy, and other supportive services, and policies which minimize intrusion into family life and reduce trauma to victims. Projects may also contract a portion of their funds for the provision of long-term therapeutic treatment services when such resources are not available from an applicant agency. Priority will be given to applications from public child protective service agencies.

The *tri-service resource team projects* are intended for communities which already have some degree of specialized resources for handling child sexual abuse cases, and will focus on improving services to families by increasing coordination and cooperation between these community agencies which have roles and responsibilities in such cases. Although funds will be awarded to a single agency in a community (which may enter into contractual relationships with other agencies), these projects must be cosponsored by at least three agencies—two of which must be: (1) The mandated public child protective services agency and (2) An office or agency within the criminal justice system which has responsibilities for the disposition of child sexual abuse cases (such as the Prosecutor's Office, Probation Department, Court or Court Services). The third cosponsor may be any other related community agency or organization (such as: health, mental health, law enforcement, education, private child welfare/family services, or other nonprofit agency), which has had prior experience and involvement in the management or treatment of child sexual abuse cases. Methods for improving coordination of sexual abuse cases received by these various agencies might include: guidelines for appropriate handling of reports of child sexual abuse, contracts of cooperation between child protective services, the police, and the prosecutor's office, cosponsorship of self-help groups or other therapeutic treatment modalities, procedures for minimizing duplication of efforts during the investigation process, alternatives to incarceration of offenders through monitoring systems for maintaining treatment accountability.

NCCAN/CB proposes to award supplementary grant funds to one of the approximately five tri-service resource team projects for the purpose of serving as a collaborative research component to the total set of projects. This component will be responsible for gathering information on the implementation and impacts of the resource team approach, especially in terms of its effects on handling of child sexual abuse cases by the criminal justice and social systems.

Although both types of service improvement projects will be involved in improving the services within their own agencies, as well as coordinating existing community resources, the specialized service component projects will emphasize the former goal while the resource team projects will focus on the latter. Both will involve intervention and treatment strategies geared toward the entire family. An effort will be made to fund projects in demographically and culturally diverse settings and priority will be given to qualified applications from mandated child protection agencies. Each applicant will be required to document the support and

future cooperation of the local child protective services agency and the criminal justice agency mandated to handle criminal complaints of child sexual abuse in order to insure that coordination of efforts will take place within the community sites of these projects.

Expected Findings: It is expected that the functioning of child protective and criminal justice agencies with regard to the investigation and disposition of child sexual abuse cases can be substantially improved by the addition of specific child sexual abuse program components not requiring substantial additional funding. Similarly, the service delivery of public and private agencies providing treatment for child sexual abuse can be more effective and responsive to the needs of families through the provision of specialized treatment services that are developed to deal with this problem. It is further anticipated that these projects will help to define the roles, responsibilities, and agreed upon procedures of various community agencies, and demonstrate the best mechanisms for enhancing their cooperation. The projects will also identify the most cost effective program components for dealing with sexual abuse cases, and the best means of installing and institutionalizing them.

Utilization: Although these projects are not research or demonstration projects, but rather service improvement projects authorized by the service provisions of Section 4(a) of Pub. L. 93–247, as amended, the proposed projects are intended to develop specialized approaches to the management and treatment of child sexual abuse cases, serve as models for the establishment of specialized program components, and suggest feasible approaches to the development and implementation of special units or components in similar service systems. It is expected that the techniques which they implement, as well as their guidelines, interagency agreements and specialized procedures will be used in preparing guidelines for future service improvement efforts and by child protective agencies to improve community coordination and handling of child sexual abuse cases.

The examples set by these projects will be communicated to: (1) The nation's over 3,000 public child protective agencies; (2) State social service administrators, legislators and policy makers; (3) Criminal justice agencies and courts; (4) Child advocacy organizations; and (5) Private treatment providers.

Dated: January 4, 1980.

Herschel Saucier,

Acting Commissioner for Children, Youth and Families.

Approved: January 14, 1980.

Warren Master,

Acting Assistant Secretary for Human Development Services.

[FR Doc. 80–1547 Filed 1–16–80; 8:45 am]

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federal register

Thursday
January 17, 1980

Part V

Department of Energy

Loans for Small Hydroelectric Power Project Feasibility Studies and Related Licensing

DEPARTMENT OF ENERGY

10 CFR Part 797

Loans for Small Hydroelectic Power Project Feasibility Studies and Related Licensing

AGENCY: Department of Energy.

ACTION: Final rule.

SUMMARY: This rule adopts policies and procedures to implement authority given to the Secretary of Energy to make loans for small hydroelectirc power project feasibility studies and related licensing under Title IV of the Public Utility Regulatory Policies Act of 1978 (Pub. L. 95–617). Notice of proposed rulemaking and public hearing thereon was issued by the Department of Energy ("DOE") on May 24, 1979.

EFFECTIVE DATE: February 19, 1980.

FOR FURTHER INFORMATION CONTACT:

Department of Energy, Farwell Smith (Office of Resource Applications), 12th and Pennsylvania Avenue, NW., Room 7104, Washington, D.C. 20461, 202–633–8910.

Department of Energy, George Samels (Office of General Counsel), 5E074 Forrestal, 1000 Independence Avenue, SW., Washington, D.C. 20585, 202–252–2924.

SUPPLEMENTARY INFORMATION:

I. Background

Title IV—Small Hydroelectic Power Projects, of the Public Utility Regulatory Policies Act of 1978, Public Law 95–617, (hereinafter, "Title IV" or "PURPA") directs the Secretary of Energy ("Secretary") to establish a program to encourage the development of small hydroelectic power projects at the site of existing dams which are not being used to generate electric power.

Title IV includes authority to the Secretary to provide direct loans for a percentage of the costs of performing feasibility studies and of obtaining the necessary licenses and approvals for small hydroelectric projects. It includes, also, authority for simplified Federal Energy Regulatory Commission ("FERC") licensing [1] and authority for Department of energy loans for construction costs.

This regulation implements the authority of the Secretary of Energy under Title IV only as regards loans for feasibility studies and for acquiring necessary licenses and approvals.

Title IV authorizes the Secretary to make loans to any municipality (as broadly defined to include a variety of State and local agencies), electric cooperative, industrial development agency, nonprofit organization, or other person (broadly defined to include a variety of entities including, among others, individuals, partnerships, associations and corporations) to assist them in defraying up to 90 percent of the costs of (1) studies to determine the feasibility of undertaking a small hydroelectric power project at an existing dam or dams, (2) preparing any application for a necessary Federal, State and local approval respecting such a project, and (3) participating in any administrative proceeding regarding such application. If the Secretary determines that the small hydreoelectric power project would not be technically or economically feasible, he or she may cancel the unpaid balance and any accrued interest on any of the above loans.

The interest rate of loans will be the discount or interest rate used at the time the loan is made for water resources planning projects under Section 80 of the Water Resources Development Act of 1974, 42 U.S.C. § 1962d–17(a). This rate has been established at 7⅛ percent for the Federal Government's 1980 fiscal year, ending September 30, 1981. The discount rate is presently permitted to change no more than ¼ percent, from one year to next, and will probably increase in the near future years. The term of these loans may not exceed 10 years.

This regulation establishes the procedure to apply for a loan, including matters of eligibility and the content of the application. Further, this regulation establishes criteria for approval of loan applications, specifies the requirements of the completed feasibility study and indicates general loan terms, including monitoring and repayment and, in certain cases, cancellation of the loan. Miscellaneous matters, such as confidentiality of information supplied in connection with a loan, are also covered. This regulation sets out priority to be accorded licensing loan applicants over applicants for feasibility study loans; and certain specified factors which may additionally affect the priority to be given an applicant.

Title IV limits loans to projects that will have installed a maximum capacity of 15,000 kilowatts or less. This regulation further limits loans to projects that will have installed capacity of 100 kilowattts or more.

Title IV further authorizes for each of Fiscal Years 1978, 1979, and 1980 $10,000,000 in loans for feasibility studies and for licensing applications, such funds to remain available until expended. Ten million dollars has been appropriated in fiscal years 1979 and 1980 for such loans.

[1] See footnote [4] below for FERC implementation of that authority.

II. Comments on Proposed Regulation

A. General

Numerous written comments were received in response to the notice of proposed rulemaking; and oral presentations were made at public hearings held June 25, 1979, at Seattle and July 2, 1979, at Boston.[2]

All comments were considered in arriving at this final rule.

The comments were generally favorable and always helpful. Quite often they covered areas of common concern, such as matters of definition or problems in the application requirements. Comments ranged from technical administrative suggestions on environmental concerns to proposals that one section or another of the country be given special consideration.

Among the comments having a common theme, no subject was raised more often than the 100 kilowatt minimum installed capacity requirement. Most comments on that minimum were that it should be lowered at least to 50 kilowatts. PURPA sets a 15,000 kilowatt maximum but leaves the setting of a minimum to this regulation. The 100 kilowatt minimum, which has been retained in this final rule, is based on DOE's experience in this field. In most cases that we have reviewed, projects near or below 100 kilowatts are not economical. Economic feasibility is a key concept in Title IV. We do not

[2] Comment was made by: American Public Power Association; R. W. Beck and Associates, Seattle, Washington; Boise, Idaho Project Board of Control; California Energy Commission; Connecticut Office of Policy and Management; John A. Dracup, San Francisco, California; Energy Research and Applications, Inc., El Segundo, California; Engineering Consultants, Inc., Englewood, Colorado; Gordon W. Hoyt, Anaheim, California; Susan Kannenberg; John S. Krikorian, Jr., Kingston, Rhode Island; Oscar Larson & Associates, Eureka, California; Maine Office of Energy Resources; Massachusetts Office of Energy Resources; Kenneth Mayo, Nashua, New Hampshire; John McNamara; New England River Basins Commission; Governor's Council on Energy, New Hampshire; New York State Energy Research and Development Authority; Northwestern Wisconsin Electric Company; Oak Ridge National Laboratory, Tennessee; Pennsylvania Department of Environmental Resources; Richard Quinzani, Boston, Massachusetts; Governor's Energy Office, Rhode Island; Rural Alaska Community Action Program, Inc.; Salt River Project Agricultural, etc., District, Phoenix, Arizona; J. Schlaikjer; Hervey C. Scudder; Norman Silberdick, Bellows Falls, Vermont; Guy Stanley; Tlingit-Haida Regional Electrical Authority, Alaska; Tudor Engineering Co., San Francisco; United States Department of the Interior; United States Environmental Protection Agency; Vermont Public Service Board; Warren Wayne; Washington (State) Department of Natural Resources; White Current Corporation, North Hartland, Vermont; Wisconsin Public Service Commission.

want to encourage people to go to the time and expense of preparing an application for a project below 100 kilowatts when chances of getting a loan are so slight.

Projects of this size, furthermore, do not generally require a feasibility study on the scale required in this regulation. Although a study for a small site would certainly require a loan far below the general $50,000 maximum, the cost of the study per kilowatt-hour of capacity would in most cases be very high. We are concerned, also, that our limited resources are used on projects having some promise of making at least the 100 kilowatt contribution.

Before proceeding to a section-by-section analysis of the comments and the changes, we should make a few general observations. A number of comments reflected ignorance of the restraints imposed on this small hydroelectric loan program by Title IV of PURPA, the authorizing legislation.

It was to avoid that misunderstanding that we reprinted (and here reprint again) the full text of Title IV. The statute specifies the maximum duration of the loans, 10 years for study and licensing loans, and their maximum amount, 90 percent of allowable costs. It requires an "existing dam" that was completed by April 20, 1977. It limits maximum installed capacity to 15,000 kilowatts.

We should emphasize, too, that this regulation deals only with feasibility study loans and licensing loans. It does not have to do with loans for construction of hydroelectric facilities. Section 403 of Title IV authorizes funds for construction loans, but, to date, no request for an appropriation of funds for construction loans has been submitted to Congress.

Finally, although this regulation attempts to set forth what a loan application should state and what a feasibility study should contain, there is no "ideal" study or application. Any study or application should provide enough information for the DOE to make the necessary evaluation of the project.

Beyond that, we leave it to the individual to determine how detailed and persuasive the document should be—and we recognize that, in the nature of things, this will be determined to some extent by the mere size of the given project.[3] Every unsuccessful applicant may request an explanation.

Section 797.41 has been added to establish a delegation of program functions from the Secretary to the Assistant Secretary for Resource Applications.

B. Purpose

Section 797.01, "General Purpose", has been changed to make clear that a licensing loan may defray a percentage of all the appropriate costs involved in pursuing the whole application process for project licensing and approval, not merely the cost of preparing an application. For example, engineer consultant services necessary to evaluate various agency comments on a license application would ordinarily be an allowable cost, as would the cost of legal counsel in intervention proceedings. Here, as throughout this revised regulation, reference has been inserted to "regional" approval considerations, in addition to Federal, State and local licensing and approval.

C. Priority

In section 797.02, "priority considerations" have been changed rather extensively as a result of comment on the proposed revisions. The holding of a FERC preliminary permit has been deleted as a basis for priority. We have concluded that a considerable percentage, possibly a majority, of applicants will have no need to establish the priority of application for FERC licensing purposes which is the sole purpose of a FERC preliminary permit. Under subchapter I of the Federal Power Act, 16 U.S.C. §§ 797(f) and 800, States and municipalities (as very broadly defined and constituting a major prospective source of small hydro applications) enjoy such preference in the issuance of FERC permits and licenses that there is scant incentive to them to obtain a preliminary permit in the absence of actual competition from a non-government applicant for a permit or license.

Deleted, too, is the priority originally proposed for non-FERC projects thought likely to win quick State and local approval. There seems little point to keeping this ground of priority if, as we anticipate, the great majority of loan applicants will come under FERC jurisdiction and will have the benefit of the simplified regulations now being developed by FERC for small hydro.[4]

We have deleted from priority consideration an applicant's need/ability to consume the planned power output. Comment received left us in doubt that this essentially economic consideration should be a ground for priority on a par with the other five basic program considerations specified at subsection 797.02(b).

Gone, too, is the proposed 35 percent allocation to licensing loans. We agree that this allocation is unnecessary in view of the Secretary's inherent authority to make appropriate adjustments responsive to program developments.

Finally, previously redundant references to review of incoming applications have been combined to indicate clearly that all applications will receive initial consideration in the order received, before being classified as to possible priority, understanding that, priority or not, some applications will prove harder and more time consuming than others to process.

D. Definitions

In section 797.03, the definition of "existing dam" has been reworded, in response to comment, to make clear that a project is not disqualified for being situated at an aqueduct outlet or canal drop, so long as the barrier to the watercourse creating the hydraulic head was constructed prior to April 20, 1977. The concept of this definition is that, in appropriate cases, such a site may itself be a small dammed impoundment within the sense of PURPA, although remote from a "mother dam", and that, as such, it may be a damsite better suited than the principal dam for small hydroelectric power development. The definition still avoids the risk that a loan may ultimately promote activities which result in drying a natural stream. As noted in footnote 3, FERC has proposed to exempt certain sites of this kind from regulation under subchapter I of the Federal Power Act. The definition should also tie in well with the PURPA Conference Committee's desire that several qualifying projects along the same waterway be treated as one for study purposes.[5]

[3] One comment stated that, although the originally proposed version of § 791.21 ("Application Requirements") might profitably be redrafted along present lines, nevertheless, "It may be of greater benefit to leave section 797.21 as is, because it forces the proposer to apply his own organizational skills to sensing an order." We chose to redraft this section.

[4] For example, Order No. 11, issued September 5, 1978, styled "Short-Form License (Minor)", covering projects of 1,500 kilowatts or less. Other regulations, either proposed by FERC or adopted, as of this writing, include Order No. 54, issued October 22, 1979: "Regulations Prescribing General Provisions for Preliminary Permit and License Applications . . ."; and, Docket No. RM 79-36, April 19, 1979: "Regulations Governing Applications for Licenses for Major Projects—Existing Dams", covering projects in excess of 1,500 kilowatts. And see Docket No. RM 79-35, April 20, 1979: "Exemptions of Small Conduit Hydroelectric Facilities from Part I of the Federal Power Act", covering facilities of 15 megawatt or less capacity which utilize only a man-made conduit operated primarily for water distribution, if located on non-Federal lands.

[5] H.R. Rep. No. 95-1750, pages 104, 106, October 10, 1978. The several projects/same waterway approach is implemented at § 797.40(b)(2) of this rule.

As reworded, the definition also makes clear that the "repairs or reconstruction" permitted under the definition of "existing dam" extend to reconstruction of a breached dam—even a badly breached one—and include renovation of abandoned hydroelectric machinery.

In line with comment which we received, the definition of "licensing loan" has been expanded to show that the loan is to defray a percentage of costs, not merely of preparing a license application but of pursuing the application process with its attendant legal, consultant, documentary, etc., expenses, as appropriate; and that license *amendment* is covered, as well as the obtaining of FERC or other license *exemption.*

Several suggestions had to be rejected in light of PURPA's express definitions of "small hydroelectric power project" (section 408(1)) and "existing dam" (section 408(6)). It was variously urged that the loan program should extend to feasibility/licensing of projects regardless of proximity to a dam and should extend to projects involving construction of a new dam. But the PURPA definitions are explicit that an existent, proximate damming structure is a basic requirement for a loan. Therefore, these suggestions cannot be acommodated within the statutory frame.

And, it was proposed that we raise the installed capacity maximum to 25,000 kilowatts in the definition of "small hydroelectric power project", so that the higher capacity will qualify for a loan. We lack authority to do so—Congress has made 15,000 kilowatts the limit under PURPA.

A related comment proposed that loans should extend to projects at dams which already generate electric power. This suggestion was based on the absence of the phrase, "existing dams *which are not being used to generate electric power"* (emphasis added) from the definition of "small hydroelectric power project" in section 406(1) of PURPA, although it appears in initial section 401 of that Act. The proponent urged, in a well-expressed comment, that this omission appears to have been legislative oversight and that in this regulation we should be no more restrictive in defining "small hydroelectric power project" than was Congress.

We have rejected the proposal to amend the definition of "small hydroelectric power project" to include dams which already generate electric power. Congress seems to have said what it intended. The establishment-of-program section, section 401, expressly restricts the program to "existing dams which are not being used to generate electric power." No provision of Title IV expressly authorizes the loaning of federal moneys for projects related to dams which already generate electric power. The House bill is described at pages 64 and 65 of the PURPA Conference Report as seeking to "develop the hydroelectric potential of existing dams which are not being used to generate electric power" and "to develop the hydroelectric potential of existing dams at which no such potential is currently in use". PURPA's definition of "existing dams" in section 408(6) speaks in terms of "installation of any small hydroelectric power project," not "increase in the installed capacity of" a small hydroelectric project. In short, the most reasonable interpretation of Title IV is that the loans are to assist study and licensing at dams that do not yet generate electric power.

E. Eligiblity Requirements

Section 797.20 of the regulation, on eligibility requirements, has been expanded to remove doubt, expressed in comment, as to what entities are eligible as "municipalities". PURPA section 408(7) carries over the Federal Power Act definition of "municipality" (16 U.S.C. 796(7)) and this regulation does the same at 797.03(f); 797.20 simply carries this over again by the reference to the broad range of state and local agencies eligible to apply as municipalities".

The citizenship requirement in this section has been reworded to avoid a misunderstanding that we regard all sites as coming under FERC licensing jurisdiction.

F. Application Requirements

Section 797.21, on application requirements, has been revised, in response to repeated suggestions, to allow applicants to submit photocopies of materials previously provided to FERC. We should note that this liberality may be of fleeting advantage, as FERC reduces its submittal requirements in compliance with Congressional mandate. We are not in a position to dispense with relatively detailed submittals; they are necessary for our prudent evaluation of the fiscal risk entailed in a direct loan program, as is the need for updating of information to reflect changes pending approval, also newly provided for in this final regulation.

We noted earlier, our extensive reworking of the general scheme of section 797.21. Additionally we have eliminated the need to state a "proposed method of repaying the loan" because we were advised that we would invariably find this answered with the words, "by check." We also eliminated the requirement of a preliminary statement of proposed construction-stage possessory and access rights. It would be premature to request this information, which would more appropriately be provided in the feasibility study. A note following subsection 797.21(a)(9) indicates those limited instances when a FERC preliminary permit will be a prerequisite to a loan.

A preliminary estimate of *value* of power (as contrasted with sale price) was added to section 797.21(b)(1)(v). This was done in response to comments that it would allow economic comparison with the cost of alternative generation in situations where sale price may be too difficult to estimate.

In subsection 797.21(b)(2), we have revised the map and picture requirements of a study loan application to indicate a preference for maps and pictures of standard quality and detail.

We have added a request, at section 797.21(b)(1)(ii), for information on reservoir use, if any. Here we are particularly concerned to learn of recreational or residential uses that may have developed at a moribund impoundment. In response, again, to comment, we have broadened section 797.21(b)(3) to garner *all* "reasonably available" reports on safety of the existing dam, rather than limit reference to Corps of Engineers reports.

We have inserted a reference to the criminal sanction under 18 U.S.C. section 1001 for intentional misrepresentation or fraud in an application.

At section 797.21(b)(6) we have added a reference to need for advance work by a diligent applicant. A *feasibility study loan* applicant is required by the Office of Management and Budget[6] to notify appropriate areawide and State clearinghouses about the intended project sufficiently in advance of DOE's action on the application for concerned governmental agencies to react to protect their own interests. We anticipate that 30 day advance notice will be required. Project notification may be initiated by an applicant by use of Standard Form 424, available from DOE offices listed later in this preface.

Finally, subsection 797.21(b)(4), requiring submission of information known by the applicant to raise substantial environmental implications, has been broadened, as a result of several comments, to include

[6] OMB Circular No. A-95, Revised (41 Federal Register 2052, January 23, 1976).

information on the presence of Federally- or State-listed endangered or threatened species of animal or plant life, and to include known involvement of critical habitat at the site.

G. Purpose of Loans

Section 797.30, on the purpose of the loans, has been rather fully reworked. The point of the section is to aid DOE's and the applicant's mutual perception of what a feasibility study should achieve. The purpose-of-loans section should give something of an overview of the whole thrust of this small hydro loan program. Although no comment was directed to need for a reworking of the section, we became concerned that, as originally drafted, it tended to obscure those objectives with a list of study subjects approaching random order. We believe that, as redrafted, it meets those objectives now.

In response to comment, subsection 797.30(a)(1)(iii) clarifies the concept of "engineering acceptability" of the proposed site for hydroelectric power development. That concept is limited for feasibility study purposes. As revised, the subsection indicates that exhaustive engineering considerations, which may be entailed in FERC licensing, are not rquired of the feasibility study.

Pursuant to comment on the dam safety issue, subsection 797.30(a)(1)(iv) has been broadened to require initial assesssment of the condition of the dam as it stands, in addition to initial assessment of hazards likely to be introduced by the project.

A new subsection, 797.30(a)(2), has been included to meet several requests for better definition of the kind of environmental and social information that the study should contain, and to indicate acceptability of certain secondary sources of such information.

In subsection 797.30(a)(3), we now limit the requirement for benefit/cost analysis to projects that do not involve project financing, but we continue to recommend inclusion of benfit/cost analysis in all studies. Where project financing is involved, the subsection, as revised, requests that the financing plan include information on contractual commitments proposed for purchase of the power output.

One comment urged that we expressly offer loans to "improve" feasibility studies. Express provision appears neither advisable nor necessary. We foresee instances when an applicant will have already assembled materials which are basic to a feasibility study but which fall short of making a case for (or against) technical and economic feasibility and environmental acceptability. It is a fine point whether an applicant in that situation would be seeking a loan to make a feasibility study or to "improve" one, but the assembling of such materials certainly would not disqualify the applicant under the provisions of this regulation.

Subsection 797.30(b) on the purpose of a licensing loan has been rephrased to correspond with preceding sections 797.01 and 797.03(k).

H. Approval Procedure

In section 797.40, on approval procedure and requirements, we have continued the shift in emphasis away from FERC preliminary permit considerations. As indicated earlier, in connection with present 797.02 and 797.21(a)(9), we anticipate that consultation with FERC, as to an applicant's need for a preliminary permit, will be selective, limited ordinarily to applicants vulnerable to the preference generally accorded States and municipalities under the Federal Power Act.

As revised, section 797.40 no longer prescribes specific Secretarial findings as to an applicant's access rights and prospects of acquiring possessory rights at the site. A requirement for specific findings as to acquisition prospects would too often involve an exercise in estimating the unpredictable. PURPA itself, in section 408(4), rather plainly envisions postponement of hard and fast decisions on acquisition until the construction loan stage. So, on reflection, the matter seems to us inappropriate for specific findings and better left for such initial consideration as may be necessary under 797.40(b)(1).

I. Loan Terms

In section 797.50, loan terms, we have corrected our error in stating that no repayment is required for the first 3 years after disbursement; none is required for the first *4* years.

Additionally, in response to comment, we have provided for loans to be evidenced by two documents, a loan agreement and a separate promissory note, and for loans in excess of the original amount of loan and/or in excess of $50,000, on certain specified conditions including the providing of collateral security, when such security is deemed necessary.[7] We would emphasize that we anticipate restricting loan increases to licensing loans primarily, if not exclusively, in situations where the difficulty in predicting such expenses as consultant and attorney fees incidental to the licensing/approval process has resulted in a justifiable underestimate of necessary expenses.

Subsection 797.50(a)(6) has been worded to indicate that a licensing loan covers the broad application process, including regional approvals.

We rejected proposals that contents and frequency of reports be specified in this rule. In a program as relatively modest as this, we would rather the loan agreement tailor those requirements to the individual account.

We rejected a proposal that 797.50(a)(4)(ii) not require liquidation of a study/licensing loan from the proceeds of construction financing. The proponent urged that significantly increased interest cost will result over the life of the construction loan, thus thwarting Congress' intention that low interest Federal financing be available to study loan and licensing loan borrowers. The proponent appeared to concede that little interest cost would be added over the former full lifetime of the typical study/licensing loan, if liquidation is required. In our view it is precisely that period that was the focus of Congressional concern in setting up this loan program.

Likewise, we rejected a request that a loan bear "simple interest", only, during its first 4 deferred years. Apart from being a reasonable condition of deferral, one wholly in keeping with standard business practice, it appears to us to be required under section 404(a) of PURPA that interest be accrued on unpaid interest during the first 4 years after execution of the loan agreement, as provided in paragraph 797.50(a)(3)(ii).

J. Assignment or Transfer

In section 797.70 we have added a prohibition on unauthorized "transfer" of the loan and its obligations, to the existing prohibition against unauthorized assignment.

K. Cancellation

Section 797.80, on cancellation of the loan obligation, has been revised in response to several suggestions. We have added, as a condition of the cancellation, the requirement at subsection (e)(3) that the borrower withdraw any pending license application for the project. We have also included, as subsection (e)(4), the provision for reinstatement of the debt which was at subsection 797.90(f) of the proposed regulation, with the additional qualification that it is for the Secretary to determine whether the forgiven borrower's interest is a substantial one in an entity that starts construction of the project to which a cancelled loan

[7] We have eliminated, as probably counterproductive, the requirement that collateral be provided for every loan. The regulation now provides for milestones and monitoring.

pertained, so as to reinstate the loan obligation.

L. Default

In section 797.90, dealing with default, we have followed the suggestion that we add insubstantiality of the default (as determined by the Secretary) as a ground for waiver of default and that we provide for the Secretarial option to restructure the loan on a mutually acceptable basis. This changes the former, more restrictive, provision that restructuring was an alternative, not an addition, to waiver.

We have declined to give a defaulter 90 days rather than 30, to pay off, as one proposal suggested. Evidently the proposal was based on concern that an unsuspecting borrower will suddenly face a deadline too short to arrange payment of the debt. We believe, on the contrary that a borrower will, typically, be aware of having lapsed into default well before the Secretary's demand for payment in full. Moreover, the Secretary has discretion when to start the deadline period running and, indeed, whether to make the demand at all. It is not to be presumed that the Secretary will seize on inadvertent, correctible defaults as ground for calling a loan.

M. Appeals

Section 797.500 is new. It provides for appeals after the loan agreement is entered into, in cases of disputes over factual determinations made by the DOE official who executed the agreement.

III. Additional Information

This rule sets out requirements for the filing and processing of applications for direct loans for small hydroelectric power project feasibility studies and related licensing and kindred matters.

The notice of proposed making of this regulation (44 Federal Register 30278, May 24, 1979) announced that requests for loans will be considered after publication of this final rule; that such requests would be acceptable prior to this publication; and that such requests must be updated to meet additional requirements of this final rule. Several such requests were received between May 24, 1979, and publication of this final rule. These applicants will be advised individually as to any necessary updating.

DOE has prepared a guide for applying for loans, the use of which we recommend to those who have not yet applied for loans. The guide is obtainable from, and requests for loans should be directed to, the DOE Regional Representative in the applicant's region, listed below.

Region I: Harold J. Keohane, Analex Bldg., Room 700, 150 Causeway St., Boston, MA 02114 (617) 223–3701.
Region II: Robert A. Low, 26 Federal Plaza, Room 3206, New York, NY 10007 (212) 264–1021.
Region III: Obra S. Kernodle III, 1421 Cherry Street, 10th Floor, Philadelphia, PA 19102 (215) 597–3890.
Region IV: Lewis Centofanti, 1655 Peachtree St., N.E., Atlanta, GA 30309 (404) 881–2838.
Region V: Robert H. Bauer, 175 West Jackson Blvd., Room A–333, Chicago, IL 60604 (312) 353–0540.
Region VI: Dan Rambo, P.O. Box 35228, 2626 West Mockingbird Lane, Dallas, TX 75235 (214) 749–7345.
Region VII: Mary O'Halloran, 324 East 11th Street, Kansas City, MO 64106 (816) 374–2061.
Region VIII: Charles F. Metzger, P.O. Box 26247 Belmar Br., 1075 South Yukon Street, Lakewood, CO 80226 (303) 234–2420.
Region IX: William C. Arntz, 111 Pine Street, Third Floor, San Francisco, CA 94111 (415) 566–7216.
Region X: Jack B. Robertson, 1992 Federal Building, 915 Second Avenue, Seattle, WA 98174 (206) 442–7289.

In accordance with section 102(2)(c) of the National Environmental Policy Act of 1969, ("NEPA"), 42 U.S.C. 4332(2)(c), DOE has determined that this final rulemaking does not constitute a major Federal action significantly affecting the quality of the human environment, because the activities included under this rule encompass only financial assistance for feasibility studies and licensing/approval endeavors. In addition, small hydroelectric power projects covered by this final rule will themselves be subject to NEPA requirements. FERC is the lead agency for licensing such projects and will have the responsibility for assuring site specific environmental review as to each such project.

In accordance with DOE Order 2030.1 implementing Executive Order 12044, "Improving Government Regulations," the Assistant Secretary for Resource Applications has determined that this regulation is significant because it is related to the National Energy Act, but will not have major economic consequences nor a substantial effect on existing energy objectives or statutes, nor adversely affect competition. Therefore, no regulatory analysis of this regulation, for major impacts, is required.

Issued in Washington, D.C. January 10, 1980.

Charles W. Duncan, Jr.,

Secretary, Department of Energy.

Text of the Authorizing Legislation

For convenience, the text of Title IV, Small Hydroelectric Power Projects, under the Public Utility Regulatory Policies Act of 1978, is printed below. Title IV includes both *Loans For Feasibility Studies*, which, with licensing loans, is the subject of this rulemaking, and *Loan For Project Costs*, for which no rulemaking has as yet been initiated.

Sec. 401. Establishment of Program

The Secretary shall establish a program in accordance with this title to encourage municipalities, electric cooperatives, industrial development agencies, nonprofit organizations, and other persons to undertake the development of small hydroelectric power projects in connection with existing dams which are not being used to generate electric power.

Sec. 402. Loans for Feasibility Studies

(a) Loan Authority.—The Secretary, after consultation with the [Federal Energy Regulatory] Commission, is authorized to make a loan to any municipality, electric cooperative, industrial development agency, nonprofit organization, or other person to assist such person in defraying up to 90 percent of the costs of—

(1) studies to determine the feasibility of undertaking a small hydroelectric power project at an existing dam or dams and

(2) preparing any application for a necessary license or other Federal, State, and local approval respecting such a project at an existing dam or dams and of participating in any administrative proceeding regarding any such application.

(b) Cancellation.—The Secretary may cancel the unpaid balance and any accrued interest on any loan granted pursuant to this section if he determines on the basis of the study that the small hydroelectric power project would not be technically or economically feasible.

Sec. 403. Loans for Project Costs

(a) Authority.—The Secretary is authorized to make loans to any municipality, electric cooperative, industrial development agency, nonprofit organization, or other person of up to 75 percent of the project costs of a small hydroelectric power project. No such loan may be made unless the Secretary finds that—

(1) the project will be constructed in connection with an existing dam or dams,

(2) all licenses and other required Federal, State, and local approvals necessary for construction of the project have been issued,

(3) the project will have no significant adverse environmental effects, including significant adverse effects on fish and wildlife, on recreational use of water, and on stream flow, and

(4) the project will not have a significant adverse effect on any other use of the water used by such project.

The Secretary may make a commitment to make a loan under this sub-section to an applicant who has not met the requirements of paragraph (2), pending compliance by such applicant with such requirements. Such commitment shall be for period of not to exceed 3 years unless the Secretary, in consultation with the Commission, extends such period for good cause shown.

Notwithstanding any such commitment, no such loan shall be made before such person has complied with such requirements.

(b) Preference.—The Secretary shall give preference to applicants under this section who do not have available alternative financing which the Secretary deems appropriate to carry out the project and whose projects will provide useful information as to the technical and economic feasibility of—

(1) the generation of electric energy by such projects, and

(2) the use of energy produced by such projects.

(c) Information.—Every applicant for a license for a small hydroelectric power project receiving loans pursuant to this section shall furnish the Secretary with such information as the Secretary may require regarding equipment and services proposed to be used in the design, construction, and operation of such project. The Secretary shall have the right to forbid the use in such project of any equipment or services he finds inappropriate for such project by reason of cost, performance, or failure to carry out the purposes of this section. The Secretary shall make information which he obtains under this subsection available to the public, other than information described as entitled to confidentiality under section 11(d) of the Energy Supply and Environmental Coordination Act of 1974, [Public Law 93–319; 88 Stat. 246].

(d) Joint Participation.—In making loans for small hydroelectric power projects under this section, the Secretary shall encourage joint participation, to the extent permitted by law, by applicants eligible to receive loans under this section with respect to the same project.

Sec. 404. Loan Rates and Repayment

(a) Interest.—Each loan made pursuant to this title shall bear interest at the discount or interest rate used at the time the loan is made for water resources planning projects under section 80 of the Water Resources Development Act 1974 (42 U.S.C. 1962 [d] 17(a)). Each such loan shall be for such term, as the Secretary deems appropriate, but not in excess of—

(1) 10 years (in the case of a loan under section 402) or

(2) 30 years (in the case of a loan under section 403).

(b) Repayments.—Amounts repaid on loans made pursuant to this title shall be deposited into the United States Treasury as miscellaneous receipts.

Sec. 405. Simplified and Expeditious Licensing Procedures

(a) Establishment of Program.—The Commission shall establish, in such manner as the Commission deems appropriate, consistent with the applicable provisions of law, a program to use simple and expeditious licensing procedures under the Federal Power Act for small hydroelectric power projects in connection with existing dams.

(b) Prerequisites.—Before issuing any license under the Federal Power Act for the construction or operation of any small hydroelectric power project the Commission—

(1) shall assess the safety of existing structures in any proposed project (including possible consequences associated with failure of such structures), and

(2) shall provide an opportunity for consultation with the Council on Environmental Quality and the Environmental Protection Agency with respect to the environmental effects of such project.

Nothing in this subsection exempts any such project from any requirement applicable to any such project under the National Environmental Policy Act of 1969, the Fish and Wildlife Coordination Act, the Endagered Species Act, or any other provision of Federal law.

(c) Fish and Wildlife Facilities.—The Commission shall encourage applicants for licenses for small hydroelectic power projects to make use of public funds and other assistance for the design and construction of fish and wildlife facilities which may be required in connection with any development of such project.

Sec. 406. New Impoundments

Nothing in this title authorizes (1) the loan of funds for construction of any new dam or other impoundment, or (2) the simple and expeditious licensing of any such new dam or other impoundment.

Sec. 407. Authorizations

There are hereby authorized to be appropriated for each of the fiscal years ending September 30, 1978, September 30, 1979, and September 30, 1980, not to exceed $10,000,000 for loans to be made pursuant to section 402, such funds to remain available until expended. There are hereby authorized to be appropriated for each of the fiscal years ending September 30, 1978, September 30, 1979, September 30, 1980, not to exceed $100,000,000 for loans to be made pursuant to section 403, such funds to remain available until expended.

Sec. 408. Definitions

For purposes of this title, the term—

(1) "small hydroelectric power project" means any hydroelectric power project which is located at the site of any existing dam, which uses the water power potential of such dam, and which has not more than 15,000 kilowatts of installed capacity;

(2) "electric cooperative" means any cooperative association eligible to receive loans under section 4 of the Rural Electrification Act of 1936 (7 U.S.C. 904);

(3) "industrial development agency" means any agency which is permitted to issue obligations the interest on which is excludable from gross income under section 103 of the Internal Revenue Code of 1954;

(4) "project costs" means the cost of acquisition or construction of all facilities and services and the cost of acquisition of all land and interests in land used in the design and construction and operation of a small hydroelectric power project;

(5) "nonprofit organization" means any organization described in section 501(c)(3) or 501(c)(4) of the Internal Revenue Code of 1954 and exempt from tax under section 501(a) of such Code (but only with respect to a trade or business carried on by such organization which is not an unrelated trade or business, determined by applying section 513(a) to such organization);

(6) "existing dam" means any dam, the construction of which was completed on or before April 20, 1977, and which does not require any construction or enlargement of impoundment structures (other than repairs or reconstruction) in connection with the installation of any small hydroelectric power project;

(7) "municipality" has the meaning provided in section 3 of the Federal Power Act; and

(8) "person" has the meaning provided in section 3 of the Federal Power Act. [End of text of Title IV.]

Accordingly, new Part 797 to Title 10, Code of Federal Regulations is added as follows:

PART 797—LOANS FOR SMALL HYDROELECTRIC POWER PROJECT FEASIBILITY STUDIES AND RELATED LICENSING

Sec.

Authority: Sec. 401 Public Utility Regulatory Policies Act of 1978, Pub. L. 95–617, 92 Stat. 3117 (16 U.S.C. 2701) and Sec. 644, Department of Energy Organization Act, Pub. L. 95–91, 91 Stat. 565 (42 U.S.C. 7101 et seq.).

§ 797.1 General purpose.

The purpose of this regulation is to establish the procedure for two kinds of loans. One is a loan to defray a percentage of the costs of studying the feasibility of developing a small hydroelectric power project in connection with an existing dam that is not being used to generate electric power. The other is a loan to defray a percentage of the costs of applying for a necessary license or other Federal, State, regional, or local approval respecting such a project and of participating in any administrative proceeding regarding such application. This regulation will also specify a) the requirements of the feasibility study, b)

the borrower's obligations under a loan, c) when the Secretary may cancel the obligation to repay the loan, and d) priorities to be accorded kinds of applications.

§ 797.2 Priority considerations.

(a) The Secretary will give applications for licensing loans priority over applications for feasibility study loans, because licensing loan applications must be based on completed feasibility studies (see § 797.40(c)(1)) and thus typically will be closer to putting power from qualified projects on line. Initial consideration will be given in the order applications are received, but the time required to process an application may vary from case to case.

(b) In determining the priority to be accorded a particular licensing or feasibility study loan application, the Secretary may take into account factors including, but not limited to, the following:

(1) The potential of the hydroelectric power project to save oil or gas.

(2) The likelihood that the project will be carried through to completion relative quickly.

(3) The need for substantial revision of the application in order to achieve compliance with this regulation.

(4) The disparity, if any, between the size of the loan sought and the size of the comtemplated project.

(5) Any evident, substantial environmental implications.

§ 797.3 Definitions.

For purposes of this part.

(a) "Small hydroelectric power project" means a hydroelectric power project that is proposed to be located at the site of an existing dam or dams in the United States, its territories or possessions, at a dam(s) not being used to generate electric power, that will use the water power potential of such dam(s), and that, when completed, will have an installed capacity of not more than 15,000 kilowatts, nor less than 100 kilowatts.

(b) "Existing dam" means any dam or barrier built across a watercourse that was completed on or before April 20, 1977, which does not require any construction or enlargement of impoundment structures (other than repairs or reconstruction) in connection with the installation of the small hydroelectric power project. "Repairs or reconstruction" as used in this subsection includes reconstruction of breached structures and renovation of machinery left in place.

(c) "Electric cooperative" means any cooperative association eligible to receive loans under section 4 of the Rural Electrification Act of 1936 (7 U.S.C. 904).

(d) "Industrial development agency" means any agency which is permitted to issue obligations the interest on which is excludable from gross income under section 103 of the Internal Revenue Code of 1954.

(e) "Nonprofit organization" means any organization described in section 501(c)(3) or 501(c)(4) of the Internal Revenue Code of 1954 and exempt from tax under section 501(a) of such Code (but only with respect to a trade or business carried on by such organization which is not an unrelated trade or business, determined by applying section 513(a) to such organization).

(f) "Municipality" means a city, county, irrigation district, drainage district, or other political subdivision or agency of a State competent under the laws thereof to carry on the business of developing, transmitting, utilizing or distributing power.

(g) "Person" includes an individual, corporation, joint stock company, partnership, association, business trust, organized group of persons (whether incorporated or not), or receiver, or trustee of any of the foregoing.

(h) "Secretary" means Secretary of Energy or his designated representative.

(i) "Statutory interest rate" means the discount or interest rate, used at the time the loan is made, for water resources planning projects under section 80 of the Water Resources Development Act of 1974, 42 U.S.C. 1962 d–17(a).

(j) "Feasibility study loan" means a loan to assist in defraying a percentage of the costs of a study to determine the technical and economic feasibility and environmental acceptability of undertaking a small hydroelectric power project at an existing dam or dams.

(k) "Licensing loan" means a loan to assist in defraying a percentage of the costs of applying for a necessary license or license amendment or other Federal, State, regional, and local approval or exemption concerning a small hydroelectric power project and the costs of participating in any administrative proceeding regarding any such application.

(l) "Loan agreement" means a contractual instrument executed between the United States as lender and a borrower, which sets forth the terms and conditions for provision of funds by the United States to the borrower incidental to a feasibility study loan or a licensing loan and for repayment of the loan by the borrower.

(m) "Commission" means the Federal Energy Regulatory Commission ("FERC").

§ 797.20 Eligibility requirements.

(a) Eligible applicants for any loan under this part may be a municipality (*i.e.*, city, county, irrigation district, drainage district or other political subdivision or agency of a State, competent as defined in § 797.3(f)), electric cooperative, industrial development agency, nonprofit organization, individual, corporation, joint stock company, partnership, association, business trust, organized group of persons (whether incorporated or not), the receiver(s) or trustee(s) of any of the foregoing, or any combination of the foregoing. Applicants may not be Federal agencies.

(b) If the proposed project site is subject to FERC licensing jurisdiction, applicants must meet any citizenship requirement of the FERC. Applicants must also meet any citizenship requirement applicable under State or local law.

§ 797.21 Application requirements.

(a) Application requirements common to feasibility study loans and licensing loans shall include financial, scheduling, and other background information in support of the application. This information will be used as a basis for the Secretary's determination whether the applicant is capable of successfully completing the feasibility study or undertaking the applicable licensing and permitting requirements and subsequently constructing and operating the proposed small hydroelectric power project. Information previously provided by a feasibility study loan applicant need not be repeated at the time of applying for a licensing loan if it is unchanged. If an applicant has already submitted an application to FERC that contains information requested in this section, applicant may attach a photocopy of what was submitted to FERC.

The information required includes the following: (1) The amount of the loan being requested and whether it is for a feasibility study or for licensing.

(2) A description of the major tasks required to perform the study or to obtain the license; a proposed schedule for completing each major task; estimates of the cost of each major task and of total costs; and the share of costs to be borne by applicant(s).

(3) A brief description of the applicant(s) that indicates its history, the kind and size of its business, or, in the case of a municipality (see definition at § 797.3(f)), the experience if any, that

the municipality has had with projects of this nature.

(4) A current financial statement that includes source of revenue and (except in the case of individual applicants) a balance sheet. The Secretary may require a licensing loan applicant to provide certification of the financial statement by a certified public accountant or equivalent certification acceptable to the Secretary.

(5) A description of any other Federal financial assistance (*e.g.*, direct loans, guaranteed loans, grants) expected to be applied for or already applied for or obtained by the applicant(s) in connection with the project.

(6) A list of all key persons who will be involved in the feasibility study or licensing effort (including any permitting effort) with their responsibilities and qualifications. This list should include any contractor and consultant whose services are proposed to be used. Information should be provided to show that they are capable of meeting the schedule within cost constraints of the loan.

(7) Affidavit(s) of United States citizenship as applicable (see § 797.20(b)).

(8) Documentation as to each applicant's authority to undertake the activities contemplated by the application. Such documentation should take substantially the following form:

(i) If an applicant is a municipality (see definition § 797.3(f)), a copy of its charter or other organization papers, duly certified by the Secretary of State, or other proper certifying officer, of the State in which it is located, with a copy of the State law(s) authorizing the proposed activities and an attested copy of the authorization to file the application.

(ii) If an applicant is a corporation, a copy of the charter or certificate and articles of incorporation, with any amendments, duly certified by the Secretary of State of the State where organized, and a copy of the by-laws. If the small hydroelectric power project would be located in a State other than that in which the corporation is organized, a certificate shall be included from the Secretary of State of the State in which the project would be located showing compliance with the laws relating to foreign corporations. There shall also be included a copy of all minutes, resolutions of stockholders or directors or other representatives of the applicant, properly attested, authorizing the filing of the application.

(iii) If an applicant is an association, a verified copy of its articles of association, if any, with an attested copy of the resolution of its governing board, if any, authorizing the filing of the application.

(iv) If an applicant is a nonprofit organization, verification of that fact.

(v) If an applicant is a business trust, a verified copy of the trust instrument and an attested copy of the resolution or other authority under which the application is made.

(vi) If an applicant is a joint stock company, a verified copy of the articles of association.

(vii) For purposes of this subsection, verification may be by affidavit of an authorized representative of an applicant; attestation shall be by the authorized officer of an applicant.

(9) The status of any application by the applicant to FERC for a preliminary permit, license or exemption for the project at the proposed site (or a statement that such application has not been made) and the status of any other application by the applicant for Federal, State, regional, or local approval of the project.

Note.—A FERC preliminary permit establishes priority of application for FERC licensing purposes. Holding such a permit is not a blanket requirement for a feasibility study loan or licensing loan under this regulation.

It is an appropriate requirement for a loan applicant (typically an applicant that is not a municipality as broadly defined, see § 797.3(f) above) whose failure to establish priority of application may result, under FERC regulation, in the ultimate award of a permit or license to another developer of the proposed site.

(10) Information provided in a *pending* application for a feasibility study loan or licensing loan under this regulation shall be updated by the applicant to show changes.

(b) Applications for *feasibility study loans* shall also include the following:

(1) A narrative description of the proposed site to be studied that should address, but not necessarily be limited to, the following, to the extent that such information is reasonably available:

(i) the number, physical composition, dimension (including height of head), general configuration, age and condition, of any dams, spillways, penstocks, powerhouses, tailraces, or other structures, to be included as part of the project;

(ii) the number, surface area, storage capacity and normal maximum surface elevation of any reservoirs to be included as part of the project and their present use;

(iii) the number, length, voltage, interconnection, age and condition of any transmission lines to be included as part of the project;

(iv) a preliminary indication of capacity potential, average annual energy generation, and the most likely customers for the power which would be produced;

(v) a preliminary estimate as to sale price or value of power;

(vi) stream characteristics (yearly flow patterns, downstream dependence on streamflows, etc.); and,

(vii) any other information that would aid the Secretary in understanding the setting in which the facility will be built, particularly those factors which may make the setting important or unique, including listing on the National Register of Historic Places of any structures or sites in the vicinity of the proposed project.

(2) Maps and pictures describing the site.

(i) U.S. Geological Survey topographical quadrangle sheets, or similar topographic maps of a State agency, if available, are preferred.

(ii) The map, as supplemented by the pictures, should indicate:

(A) The location of the proposed project with reference to the affected stream or other body of water and, if possible, to a nearby town or any other permanent monuments or objects that can be noted on the map and recognized in the field.

(B) The approximate relative locations of the principal project features.

(C) The approximate proposed project boundary. This should also indicate both non-Federal lands necessary for the project and lands of the United States (including reservations).

(3) Any report on the safety of the dam or dams at the project site reasonably available to the applicant.

(4) A description of substantial environmental implications known to the applicant, including information regarding the presence of any Federally or State-listed endangered or threatened species of animal or plant in the area of the project, critical habitat involved, if any, and the possible need to accommodate migratory fish by installation of fish ladders.

(5) Information on how the applicant will have access to the proposed project site to perform the study.

(6) A copy of the project notification sent by applicant for review by areawide and State clearinghouses, as required by Office of Management and Budget Circular No. A–95, Revised (41 FR 2052, January 13, 1976).

(c) Applications for a *licensing loan* shall include in addition to the information specified in paragraph (a) of this section, a copy of a completed feasibility study acceptable to the

Secretary and conforming to the requirements indicated in § 797.30.

(d) In addition to the above required information the loan applicant shall supply such other information as the Secretary may deem necessary to consider the request for a loan.

(e) The application shall be signed by the applicant(s) or on behalf of an applicant by an authorized representative. (*Note:* Title 18 United States Code, section 1001 provides criminal penalties for fraud and intentional false statements in information submitted in such an application.)

(f) Every applicant whose application has been rejected will be informed, upon request, of the reason for rejection. The rejection is not a bar to submission of an appropriately revised application.

§ 797.30 Purpose of loans.

(a) Feasibility Study Loans.

(1) The purpose of a feasibility study loan is to help to defray expenses to be incurred in preparing a study of the small hydroelectric power project proposed by an applicant. Broadly stated, the goal of that study is to determine, through engineering and economic analysis and consideration of environmental and institutional requirements, whether the project is technically and economically feasible and environmentally sound as a supplier to an existing power grid or as an independent contributor of power for local applications or a combination of both. Accordingly, each study should address, but is not limited to, the following:

(i) Site description not previously supplied under § 797.21(b)(1)(i)–(iii) and 797.21(b)(2).

(ii) Estimated performance characteristics of the facility, including potential peak power production, and estimated average annual energy production.

(iii) Engineering acceptability of the site for hydroelectric power development.

Note.—For an existing dam, this should not ordinarily require extensive detailed field investigation (*e.g.*, subsurfave geotechnical investigation) nor preparation of detailed working drawings and specifications of the kind that may be required in connection with a FERC license application.

(iv) Initial assessment of the condition of the dam and of the safety hazards, if any, likely to be introduced by the installation or rehabilitation of the power plant and appurtenances.

(v) Availability of a suitable turbine(s), generator(s) and accessories required for the facility.

(vi) Plan for using or marketing the power including description of present and prospective power user groups and estimated revenues or value to be derived from power produced.

(vii) Plan for transmitting power from the project to intended user.

(viii) Anticipated annual operation and maintenance costs.

(ix) Anticipated project life.

(x) Need, if any, to acquire land or any interest in land or in project structures, or other land rights or water rights, to construct and operate the facility, and their availability and estimated cost.

(xi) Environmental and related considerations as indicated in paragraph (a)(2) of this section.

(xii) Estimates of costs of obtaining Federal, State, regional and local license and/or approval necessary for construction and operation of the facility, including legal and consultant expenses incidental to administrative proceedings. *Note* the importance of early identification of all such agencies and of advance contact with them to determine turn-around time.

(xiii) Financial analysis as indicated in paragraph (a)(3) of this section.

(xiv) Total estimated cost of the project and cost per kilowatt-hour produced.

(xv) Schedule for putting power on line.

(2) The study should identify probable environmental and social impacts of the project. In particular, the study should analyze the likely effect of construction and of proposed mode(s) of operation of the facility on water resources of the project area (including water quality and effects on the current uses of the reservoir, and on major downstream uses); on recreation; and on plant and local or migratory animal wildlife, listing the presence of any Federally- or State-listed endangered or threatened species. The study should also indicate the involvement of any critical habitat and the involvement of any site included on, or eligible for, the National Register of Historic Places. *Note:* Applicants should consult with the Department of Energy early in the feasibility study to obtain further guidance on the scope and level of detail required for a specific project. In general, this aspect of the feasibility study will be based on available information supplemented by reconnaissance level site specific information as necessary to identify probable environmental impacts. Further, this aspect does not involve the preparation of an environmental impact statement or an environmental assessment pursuant to the requirements of the National Environmental Policy Act of 1969 ("NEPA") (42 U.S.C. 4321 *et seq.*) and the regulations (40 CFR Parts 1500–1508) of the Council on Environmental Quality for implementing the procedural provisions of NEPA. Applicants should be aware that the licensing of small hydroelectric power projects will require a site specific NEPA review that will be under the jurisdiction of the Federal Energy Regulatory Commission.

(3) In those cases where construction of the facility will require project financing, the study should include a cash flow statement covering the first ten operating years and a financing plan. The plan should use realistic assumptions regarding interest rates and debt amortization, and should detail contractual commitments proposed to be obtained for purchase of power output of the project. For projects not requiring project financing, an economic benefit/cost analysis should be provided. *Note:* Although a benefit/cost analysis is not required for a project which uses project financing, such an analysis is often of assistance in evaluating such a project, and its inclusion is encouraged.

(b) Licensing Loans.

The purpose of a licensing loan is to assist in defraying a percentage of the costs of applying for a necessary license or license amendment or other Federal, State, regional, and local approval or exemption respecting a small hydroelectric power project and the cost of participating in any administrative proceeding regarding any such application.

§ 797.40 Approval procedure and requirements.

(a) Consultation with FERC. Before making a feasibility study loan or a licensing loan, the Secretary will consult with FERC to the extent the Secretary deems necessary to determine whether the loan would be inadvisable unless the applicant holds a preliminary permit from FERC under Subchapter I of the Federal Power Act (16 U.S.C. § 791a, and following) for the proposed project. The Secretary will not make the loan if the Secretary believes it to be inadvisable for lack of that permit. See note to § 797.21(a)(9).

(b) Feasibility Study Loans.

(1) Before issuing a feasibility study loan, the Secretary must make the following findings, which will be based upon the Secretary's evaluation of the information provided in the loan application or otherwise available:

(i) That there exists a reasonable likelihood that the applicant or other person who will undertake the study is capable of performing it.

(ii) That the applicant will repay the loan.

(iii) That the project may be found to be both technically and economically feasible and environmentally acceptable. The determination of economic feasibility will include consideration of costs associated with environmental and safety factors.

(iv) That all requirements of this regulation, and of Title IV of the Public Utility Regulatory Policies Act of 1978, pertaining to the issuance of the feasibility study loan, have been found to be satisfied.

(2) In cases where there are two or more proposed projects located upon the same waterway, the Secretary may approve one loan for a single feasibility study dealing with all such projects (in which the persons proposing the projects will jointly participate with rights and obligations hereunder exactly the same as if their participation were on a separate basis) even though the projects are proposed by different persons, if the Secretary finds that to do so would avoid unnecessary duplication of effort and costs and would provide adequate information to make a determination concerning the feasibility of all such projects.

(c) Licensing Loans.

Prior to the issuance of a licensing loan, the Secretary must make the following findings, which will be based upon the Secretary's evaluation of the information provided in the loan application and accompanying feasibility study, or otherwise available:

(1) That the applicant has submitted a feasibility study which substantially conforms to the requirements and purpose indicated in section 797.30 and tends to establish that the proposed small hydroelectric power project is technically and economically feasible and environmentally acceptable. The determination of economic feasibility will include consideration of costs associated with environmental and safety factors.

(2) That there exists a reasonable likelihood that the applicant will repay the loan.

(3) That all requirements of this regulation, and of Title IV of the Public Utility Regulatory Policies Act of 1978, pertaining to the issuance of the licensing loan, have been satisfied.

(d) Additional Considerations as to Feasibility Study Loans and Licensing Loans.

In determining whether or not to make a feasibility study loan or licensing loan, as well as in determining the percentage of costs such loan will defray, the Secretary may take into consideration the cost of the work as it relates to the size and output of the proposed hydroelectric power facility, and such other matters as in the Secretary's judgment bear on the ultimate success or failure of the proposed small hydroelectric power project. See, also, § 797.50(c), regarding loan limits.

(e) Site Visits. In making the determinations referred to in this section, the Secretary may consider information provided by a visit to the proposed site by the Secretary or his or her representative.

§ 797.41 Delegation of authority.

(a) Pursuant to the authority vested in the Secretary of Energy ("Secretary") and by Section 642 of the Department of Energy Organization Act (Pub. L. 95–91), there is hereby delegated to the Assistant Secretary for Resource Applications the authority to:

(1) Make feasibility study loans and licensing loans, and cancel the unpaid balance and any accrued interest on such loans, pursuant to the Small Hydroelectric Power Projects Program authorized in Title IV of the Public Utility Regulatory Policies Act of 1978 (Pub. L. 95–617) ("PURPA") and otherwise administer such Program;

(2) Promulgate such rules and regulations as necessary and appropriate for the Assistant Secretary to perform his or her functions under Title IV of PURPA;

(3) Sign documents, for publication in the **Federal Register**, that are necessary for the Assistant Secretary to perform his or her functions under Title IV of PURPA;

(4) Take such other action as the Secretary or the Secretary's authorized delegates may, from time to time, direct or authorize.

(b) The authority delegated to the Assistant Secretary for Resource Applications may be further delegated, in whole or in part.

(c) In exercising the authority hereby delegated or as redelegated pursuant to this section, the delegate(s) shall be governed by the rules and regulations of the Department of Energy and the policies and procedures prescribed by the Secretary's delegate.

(d) Nothing in this delegation by the Secretary shall preclude the Secretary from exercising any of the authority so delegated whenever, in the Secretary's judgment, the Secretary's exercise of such authority is necessary or appropriate to administer the functions vested in the Secretary.

§ 797.50 Loan agreement and terms.

(a) A loan agreement, and a promissory note securing performance of that agreement, shall be executed in writing between the borrower and the Secretary. In addition to other provisions the Secretary may deem appropriate, the loan agreement and the promissory note shall provide as follows, either at full length or by incorporation by reference to terms of the other of the two documents.

(1) The borrower agrees to repay the loan of funds provided by the Secretary, unless the Secretary forgives repayment as provided in paragraph (a)(4)(i) of this section.

(2) The interest rate on the loan will be the statutory interest rate.

(3) The loan shall be repaid over a maximum period of 10 years as follows:

(i) No payments of principal or interest are required for the first 4 years from the date of execution of the loan agreement.

(ii) Beginning on the 4th anniversary date, the accrued interest, which will include interest charged on unpaid interest, shall be added to the outstanding principal balance and ⅓ of that total shall be due at such time.

(iii) Each anniversary date thereafter, ⅓ of the total computed in subparagraph (ii) above shall be due plus all interest accrued in the previous year on the unpaid balance of the loan.

(iv) Prepayments may be made at any time without penalty.

(4) The provisions of this subsection above shall be altered by the following circumstances:

(i) The Secretary forgives repayment of interest and principal as permitted in § 797.80.

(ii) Construction is undertaken on the proposed hydroelectric power project, in which event the outstanding balance of the feasibility study and/or licensing loan should be part of the financing for such project and the loan repaid out of the proceeds of any construction loan. To insure compliance with this provision, the Secretary shall have the option of accelerating the repayment of any loan made under this regulation and demanding payment in full any time after the expiration of 60 days from the date construction has begun on the project.

(5) Payments required by the loan agreement, if not made when due, shall accrue interest at a specified rate, which shall be not less than 10 percent per annum.

(6) The loan may be used by the borrower to defray up to 90 percent of the costs of a feasibility study or of the costs of applying for a necessary license or license amendment, other Federal, State, regional, and local approval or exemption respecting the project, and of participating in any administrative proceeding regarding such application. No part of the loan shall be used to defray any fee charged by any Federal,

State, regional or local agency as a condition of receiving a license, amendment, or other approval or exemption, or any cost associated with a finder's fee. The loan may defray reasonable and customary costs directly related to the project and entailed in the engineering, financial, legal, environmental, social and institutional considerations necessary to the study on to the licensing or approval endeavors of the borrower.

(7) The borrower will make periodic reports, as required, regarding the progress of the feasibility study or licensing or approval activities.

(8) Requests for disbursements at closing and thereafter shall be supported by such documents and by such indications of progress as the secretary may require.

(9) Costs allowable under paragraph (a)(6) of this section and incurred by a borrower prior to signing the loan agreement may be credited toward the borrower's share of costs. In no case will such costs be reimbursable from proceeds of the loan.

(b) The documents shall also provide, either at full length or by incorporation by reference, for monitoring and audit (see § 797.60), assignment or transfer (see § 797.70), default (see § 797.90), and appeals (see § 797.500).

(c) The Secretary will not increase the amount of a feasibility study loan or licensing loan, nor make a feasibility study loan or licensing loan in excess of $50,000, unless in the Secretary's judgment good cause is shown. In that event, the Secretary may require of the borrower such additional supporting covenants, collateral security arrangements, and contribution to the project as the Secretary deems necessary to protect the interests of the United States.

§ 797.60 Project monitoring and audit.

The borrower shall keep such records concerning the small hydroelectric power project as are required by generally accepted accounting principles, and such other records as the Secretary may deem necessary. The Secretary may have access, for the purpose of audit and examination, to any pertinent records or other documents of the borrower during the regular business day, and may require that copies of such documents be provided to the Department of Energy by the borrower.

§ 797.70 Assignment or transfer of loan.

Assignment or transfer of the loan and obligations contained thereunder may be made only with the written consent of the Secretary.

§ 797.80 Cancellation.

(a) The Secretary may cancel the unpaid balance and any accrued interest on any feasibility study loan or licensing loan if the Secretary determines on the basis of the study, or on the basis of any other information available to the Secretary, that the small hydroelectric power project would not be technically or economically feasible or environmentally acceptable. The Secretary's determination to cancel the loan may be made prior to the completion of the study or afterwards.

(b) In determining economic feasibility, the Secretary shall be guided by the Secretary's determination of the ability of the proposed project to support financing appropriate to carry out the project and available to the applicant for the project under reasonable terms and conditions.

(c) The Secretary may cancel the unpaid balance and any accrued interest on a loan to a borrower who, in the Secretary's judgment, has been or will be unable to obtain a necessary license respecting the project, or any right necessary to construct and operate the project, for a reason beyond the borrower's control and despite borrower's good faith effort to do so.

(d) The Secretary will not cancel the unpaid balance and accrued interest on any feasibility study or licensing loan if the Secretary finds that the borrower, in applying for the loan. (1) failed to provide information reasonably available to such borrower that would have indicated that there was not a reasonable likelihood the project would be found to be technically and economically feasible and environmentally acceptable, or (2) withheld information indicating that the borrower would be unable to obtain a license, approval or right necessary to the project.

(e) It shall be a condition of cancellation of unpaid balance or accrued interest under this section that:

(1) The Secretary's obligation to disburse funds under the loan agreement shall terminate.

(2) A feasibility study produced under a feasibility study loan made to the borrower pursuant to this regulation shall become property of the United States.

(3) The borrower shall withdraw any pending license application for the project.

(4) If during the term of a cancelled loan the borrower, or an entity in which the borrower has a substantial interest, as determined by the Secretary, starts construction of the small hydroelectric power project to which the loan pertained, unpaid principal and interest to date shall become due and payable.

§ 797.90 Default.

(a) If the borrower fails to perform the terms and conditions of the loan agreement or any related document, the borrower shall be in default and the Secretary shall have the right, at the Secretary's option, to accelerate the indebtedness and demand full payment of all amounts outstanding, both principal and interest, under the loan.

(b) No failure on the part of the Secretary to make demand at any time shall constitute a waiver of the rights held by the Secretary.

(c) Upon demand by the Secretary, the borrower shall have a period of not more than 30 days from the date of demand to make payment in full because of default.

(d) If the failure on the part of the borrower to perform the terms and conditions of the loan agreement, or related document, does not constitute an intentional act, but is brought about as a result of circumstances largely beyond the control of the borrower, or is deemed by the Secretary to be insubstantial, the Secretary may elect, at the Secretary's option, to waive the default and restructure the repayment required by the loan agreement in any mutually acceptable manner.

(e) Should the borrower fail to pay after demand as provided in paragraph (c) of this section, the Secretary shall undertake collection in accordance with the terms of the loan agreement and the applicable law.

§ 797.100 Disclosure.

Subject to the requirements of law and in accordance with Department of Energy ("DOE") regulations concerning public disclosure, trade secrets, commercial and financial information, and other information or data concerning the project that the applicant submits to DOE in writing on a privileged or confidential basis before or during the project will not be disclosed by DOE without prior notification to the applicant. Any applicant asserting that the information is privileged or confidential shall appropriately identify and mark such information.

§ 797.200 Noninterference with Federal, State, regional, and local requirements.

Nothing in this regulation shall be construed to modify requrements imposed on the borrower by Federal, State, regional, and local government agencies in connection with permits, licenses, or other authorizations to construct or finance small hydroelectric power projects.

§ 797.300 Overall program considerations.

Nothing in this regulation shall be interpreted to restrict the Secretary, in making the various determinations provided for in this regulation, from taking into account considerations relating to the small hydroelectric power project loan program as a whole.

§ 797.400 Nondiscrimination in federally assisted programs.

(a) Applicants and recipients of Federal assistance from DOE are obligated to comply with civil rights requirements of the following public laws: Title VI of the Civil Rights Act of 1964; Title IX of the higher Education Amendments of 1972; Section 16 of the Federal Energy Administration Act of 1974; Section 401 of the Energy Reorganization Act of 1974; Section 504 of the Rehabilitation Act of 1973; and the Age Discrimination Act of 1975.

(b) To be in compliance with civil rights requirements, an applicant/recipient, among other obligations, must—

(1) Submit a written assurance that the program or activity will be operated in a manner that does not exclude from participation in or deny the benefits or services to individuals on the basis of race, color, national origin, sex, age, or handicap;

(2) Designate the person responsible for coordination of activities to carry out its civil rights compliance responsibilities; and

(3) Take appropriate initial and continuing steps to notify participants, beneficiaries, applicants and employees that it does not discriminate on the basis of race, color, national origin, sex, age, or handicap.

§ 797.500 Appeals.

Any dispute about a question or fact arising under the loan agreement shall be decided in writing by the DOE official who executed the agreement, or his successor. The borrower may, within 14 calendar days after receipt of the decision, make a written request to that official to reconsider the decision. The decision on the request for reconsideration, which also shall be in writing, may be appealed in writing by the borrower, within 30 calendar days after receipt, to the Chairman, Board of Contract Appeals, Department of Energy, Washington, D.C. 20545. That Board, when functioning to resolve the dispute, shall proceed in the same general manner as when it presides over appeals involving contract disputes. The decision of the Board on the dispute shall be the final decision of the Secretary.

[FR Doc. 80-1571 Filed 1-16-80; 8:45 am]

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federal register

Thursday
January 17, 1980

Part VI

Department of Health, Education, and Welfare

National Institutes of Health

Recombinant DNA Research; Actions Under Guidelines

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

National Institutes of Health

Recombinant DNA Research; Actions Under Guidelines

AGENCY: National Institutes of Health, PHS, HEW.

ACTION: Notice of actions under NIH Guidelines for Research Involving Recombinant DNA Molecules.

SUMMARY: This notice sets forth actions taken by the Director, NIH, under the 1978 NIH Guidelines for Research Involving Recombinant DNA Molecules (43 FR 60108).

EFFECTIVE DATE: January 17, 1980.

FOR FURTHER INFORMATION CONTACT: Additional information can be obtained from Dr. William J. Gartland, Office of Recombinant DNA Activities (ORDA), National Institutes of Health, Bethesda, Maryland 20205, (301) 496-6051.

SUPPLEMENTARY INFORMATION: I am promulgating today several major actions under the NIH Guidelines for Research Involving Recombinant DNA Molecules. These Guidelines (43 FR 60108) include procedures for changing the Guidelines. As detailed in Section IV-E-1-b-(1) of the Guidelines, this involves: (1) publication of the proposed changes in the **Federal Register** for public comment, at least 30 days prior to a meeting of the NIH Recombinant DNA Advisory Committee (RAC); (2) consideration of the proposed changes by the RAC; and (3) publication in the **Federal Register** of the final decision by the Director, NIH.

In accordance with these procedures, proposed changes in the Guidelines appeared in the **Federal Register** on January 15, 1979 (44 FR 3226), were considered by the RAC at its February 16-17, 1979, meeting, and were promulgated by the NIH Director in the **Federal Register** on April 11, 1979 (44 FR 21730).

Proposed changes in the Guidelines appeared in the **Federal Register** on April 13, 1979 (44 FR 22314), were considered by the RAC at its May 21-23, 1979, meeting, and were promulgated by the NIH Director in the **Federal Register** on July 20, 1979 (44 FR 42914).

Proposed changes in the Guidelines appeared in the **Federal Register** on July 31, 1979 (44 FR 45088), and were considered by the RAC at its September 6-7, 1979, meeting. Rather than promulgating the recommended changes, the Director, NIH, instead issued them for 30 days of additional public comment in the **Federal Register** on November 30, 1979 (44 FR 69210). Final action on these proposed changes has not yet been taken.

Proposed changed in the Guidelines appeared in the **Federal Register** on November 1, 1979, (44 FR 63074) and were considered by the RAC at its December 6-7, 1979, meeting. This notice discusses the four "major actions" that were recommended favorably at the December 6-7, 1979, RAC meeting. Part I of this announcement provides background information on the actions; and Part II provides a summary of the major actions promulgated today. In accordance with Section IV-E-1-b of the NIH Guidelines, I find that these actions comply with the Guidelines and present no significant risk to health or the environment.

I. *Decision on Actions Under Guidelines*

I-A. *Amendment of Sections III-B-2, III-C-5, and III-C-6 of the Guidelines*

A proposal appeared in the **Federal Register** on November 1, 1979, to amend Sections III-B-2, III-C-5, and III-C-6 to change the words ". . . may be inserted into a lambdoid phage vector or into a vector from a certified EK2 host-vector system and propagated . . ." to ". . . may be inserted into a vector and propagated. . . ."

No comments were received during the 30-day comment period.

At the December 6-7, 1979, RAC meeting support was voiced for these changes dealing with "return to host of origin" experiments. It was stated that the changes would give scientists more flexibility in designing experiments without significantly affecting safety in any way. A motion to accept these changes passed by a vote of 15 in favor and none opposed, with 3 abstentions.

I accept this recommendation.

I-B. *Transfer of Cloned Segments of Anabaena Into Klebsiella*

A request from Dr. Robert Haselkorn of the University of Chicago to transfer cloned segments of DNA from the cyanobacterium *Anabaena* into *Klebsiella* was discussed at the September 6-7, 1979, RAC meeting, when the proposal was not accepted pending further information from Dr. Haselkorn.

Notice was placed in the **Federal Register** on November 1, 1979, that the RAC would be considering this again at its December 6-7, 1979, meeting.

No comments were received during the 30-day comment period.

Copies of a November 16, 1979, letter from Dr. Haselkorn in response to the questions raised at the September 6-7, 1979, RAC meeting were mailed to the RAC members prior to their December 6-7, 1979, meeting.

At the December 6-7, 1979, RAC meeting it was pointed out that Dr. Haselkorn's November 16 letter clarifies that he is using an *Anabaena cylindrica* strain that does not produce a toxin. It was stated that the experiment is scientifically important and seems safe. The use of conjugative plasmids has a precedent in the previous approval by the RAC of the use of the Ti plasmid of *Agrobacterium tumefaciens* in certain experiments. A motion to approve the requested experiments to be performed at P2 physical containment passed by a vote of 12 in favor, none opposed, with 4 abstentions.

I accept this recommendation.

I-C. *Request for Exception to Prohibition to Clone Foot-and-Mouth Disease Virus in E. coli K-12*

Notice was placed in the **Federal Register** on November 1, 1979, that the RAC would be considering at its December 6-7, 1979, meeting a requested exception to a prohibition in order to clone foot-and-mouth disease virus (FMDV) in *E. coli* K-12.

No comments were received during the 30-day comment period.

FMDV is classified as a Class 5 agent in the Center for Disease Control's "Classification of Etiologic Agents on the Basis of Hazard" (4th edition, July 1974). The NIH guidelines prohibit, in Section I-D-1, "Formation of recombinant DNAs derived from the pathogenic organisms classified [1] as Class 3, 4, or 5 [2] or from cells known [2A] to be infected with such agents, regardless of the host-vector system used." However, "experiments in these categories may be excepted [4] from the prohibitions (and will at that time be assigned appropriate levels of physical and biological containment) provided that these experiments are expressly approved by the Director, NIH, with advice of the Recombinant DNA Advisory Committee after appropriate notice and opportunity for public comment."

By law, "no live virus of foot-and-mouth disease may be introduced for any purpose into any part of the mainland of the United States except coastal islands . . . " (21 U.S.C. 113a). The only research on foot-and-mouth disease virus in the United States is carried out at the Plum Island Animal Disease Center of the U.S. Department of Agriculture, located on Plum Island, about 1.5 miles from the eastern tip of Long Island in the State of New York. The Plum Island Animal Disease Center, which occupies essentially all of Plum Island, was established in 1954 for the study of exotic diseases of domestic animals.

Foot-and-mouth disease is a highly contagious viral disease of cattle, swine, sheep, and other cloven hoofed animals. There were 9 outbreaks of this disease in the United States between 1870 and 1929. Since that time stringent quarantine measures and inspection at ports of entry have kept this country free of the disease.

Foot-and-mouth disease is characterized by the formation of vesicles on the mucous membranes of the mouth, on the nose, and on the skin between and adjacent to the claws of the feet. Transmission is primarily from the infected animal itself, especially during the early febrile stage when virus is present in the blood and all organs, tissues, secretions and excretions. The spread of FMD among animals in close proximity probably occurs chiefly through virus in saliva and foot lesions. Excreted virus, and virus in dried blood, in carcasses, and on hay, soil, wood, clothing, and other objects, persist for long intervals, serving as a reservoir of infection.

Foot-and-mouth disease virus is a member of the rhinovirus genus of the picornavirus group of single-stranded RNA viruses. The single-stranded RNA (molecular weight $=2.6\times10^6$ daltons) acts in vivo as a template for both viral RNA replication and for translation.

There are 33 or more natural hosts (all cloven-footed) for FMD. Immunological complexity in FMD is characterized by seven types of virus and by approximately 65 subtypes. Animals immune to one type are susceptible to the other six types.

Foot-and-mouth disease virus contains primarily four capsid proteins—VP_1, VP_2, VP_3 and VP_4 (molecular weights approximately 33,000, 30,000, 27,000, and 8,000). An experimental vaccine containing purified VP_3 has been shown to protect swine against foot-and-mouth disease.

Prior to the December 6–7, 1979, RAC meeting, the Committee members had been sent copies of a Memorandum of Understanding and Agreement (MUA) entitled "Cloning and Expression in *E. coli* of the VP_3 protein of Foot and Mouth Disease Virus," as well as numerous other background documents dealing with foot-and-mouth disease.

As noted in the MUA, "Genentech Inc., South San Francisco, California, and the Plum Island Animal Disease Center, Greenport, New York, are joining in a research effort with the goal of the eventual production of a viral subunit vaccine for this disease." Stage I of the scientific plan involves "the production of double stranded cDNA from intact 37S viral RNA isolated from FMD virions. Using reverse transcriptase, *E. coli* polymerase I and various DNA oligonucleotide primers, we will produce a double stranded cDNA that contains the entire genome in subgenomic fragments. With these fragments a gene bank can be constructed of FMD virus sequences attached to the plasmid pBR322 . . . This plasmid preparation will be transformed into *E. coli* K–12 and plasmid containing bacteria selected on suitable agar plates. The colonies obtained will be transferred to filters and screened for the presence of FMD sequences using hybridization techniques against radiolabelled FMD virus cDNA. . . . Colonies containing FMD virus sequences will then be grown up and analyzed. Plasmids demonstrated to contain subgenomic FMD virus sequences of interest will be prepared. This preparation will be tested for the lack of infectious material by Plum Island researchers. . . . All of the cloning experiments with cDNA will be done in the foreign animal disease control laboratories on Plum Island. These are maintained at greater than the P3 requirements of the NIH Guidelines."

The MUA also describes Stage II to be "carried out at Genentech Inc., South San Francisco, California. Various plasmid DNA's, demonstrated to contain only subgenomic fragments, will be transferred to Genentech. . . ." Stages III and IV are also described. The MUA, signed by the principal investigators at Plum Island Animal Disease Center and Genentech, Inc., includes certification from the Institutional Biosafety Committees at both Plum Island and Genentech. The proposed work was endorsed in an October 23, 1979 memorandum from the office of the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture which states that "the proposed work plan as presented has been reviewed and considered by Veterinary Services and the Parent Committee on Foreign Pathogens and Vectors. Taking into account the safety procedures that are to be followed to assure that cultures of the organism *E. coli* containing the specific protein VP_3 are free of any infectious material that could originate from the FMD virus, or from any other exotic pathogens, we have no objections to this work being conducted, or to the transfer of the specified noninfectious protein of the FMD virus to Genentech Laboratories, South San Francisco, California."

At the December 6–7, 1979, RAC meeting, Dr. J. J. Callis, Director, and Howard Bachrach of Plum Island Animal Disease Center (PIADC), and Dr. Michael Ross of Genentech, Inc., answered questions from the RAC about the proposal. Dr. Callis said that currently 800 million doses of foot-and-mouth virus vaccine are used annually throughout the world.

During the extensive discussion of this proposal at the meeting, RAC members endorsed the enormous benefits to the world that could accrue from this project. It was stated that the plan seems safe as long as no potentially infectious foot-and-mouth virus leaves Plum Island. A concern was expressed that it would be theoretically possible for separate subgenomic pieces of foot-and-mouth virus cDNA, after they left Plum Island spliced to pBR322, to recombine with each other to regenerate a complete cDNA copy of foot-and-mouth disease virus. While it was agreed that the probability of this occurrence was exceedingly low, it was also agreed that the probability would be zero if a condition were placed on the work that the clones to be approved for removal from Plum Island shall not contain among them, collectively or individually, the full genome of the foot-and-mouth disease virus.

A motion was passed by a vote of 17 to zero, with one abstention, that the RAC "approve the formation of recombinants between foot-and-mouth disease virus and plasmid pBR322 as outlined in Stage I of the scientific plan of Document #763, to take place at Plum Island."

A motion was passed by a vote of 13 in favor, 4 opposed, with 1 abstention

that "While the Committee approves the entire project in principle, it is recognized that data from the first stage must be evaluated prior to removal of any clones from Plum Island. Accordingly, a Working Group shall be formed to examine data on the infectivity of subgenomic portions of the foot-and-mouth disease virus and to examine the testing data on infectivity of the clones produced at Plum Island. The collection of clones to be approved for removal from Plum Island shall not contain among them, collectively or individually, the full genome of the foot-and-mouth disease virus. This Working Group shall:

"(a) report back to the full RAC on the infectivity data. RAC will then consider approval for further stages of the experiment.

"(b) recommend to the RAC procedures for continued monitoring of these experiments."

Dr. Campbell stated that it was the sense of the RAC that this motion constituted the "major action" and that future recommendations of the RAC approving further stages of the experiment would be "minor actions."

The RAC further voted (9 in favor, 7 opposed, with 2 abstentions) that once the clones are transferred to Genentech, experiments with them can be carred out at P1+EK1 containment.

The Decision of the Director, NIH, is to accept the first recommendation of the RAC (vote: 17–0–1) allowing the cloning of foot-and-mouth disease virus in the EK1 host-vector system consisting of an *E. coli* K–12 host and the vector pBR322, all work to be done at the Plum Island Animal Disease Center. I also accept the second recommendation of the RAC (vote: 13–4–1) that first a working group of the RAC and subsequently the full RAC examine data arising from the foot-and-mouth disease virus recombinant DNA work on Plum Island prior to the shipment of any clones off of Plum Island. I am not accepting, at present, the third recommendation of the RAC (vote: 9–7–2) concerning the containment levels for the work to be done at Genentech after the clones are sent from Plum Island. Since acceptance of the second recommendation entails review of data by a working group of the RAC and by the full RAC prior to any shipment of foot-and-mouth subgenomic virus clones from Plum Island, I will reserve my decision on the appropriate containment level for work with these clones at Genentech until the RAC has examined these data.

Assessment of the potential environmental impact involved in the above recommendations touched upon the following considerations:

Work has proceeded for many years on Plum Island with foot-and-mouth disease virus without any adverse environmental impact beyond the island. In September, 1978, there was an escape from the Plum Island high-security laboratory to other cattle on the island. The infection did not spread beyond Plum Island. Following this incident, there were a number of extensive analyses of safety at PIADC, including reports from: ad hoc Plum Island committees; the U.S. Department of Agriculture Office of Investigations; and an External Safety Review Committee.

Improvements in safety at Plum Island which occurred subsequent to September 1978 are documented in: a January 12, 1979, memorandum from Dr. J.J. Callis, Director of PIADC; a July 12, 1979, memorandum from External Safety Review Committee members; and a September 1979 PIADC Status Report. Among the changes: training and operating procedures were improved; PIADC biological safety regulations were rewritten; air filtration system gaskets were changed and the system is now checked daily; directional airflow is frequently monitored; and 17 new Class II biological safety cabinets were installed.

All of the recombinant DNA work involving foot-and-mouth disease virus at PIADC will be done at a level of physical containment greater than P3. That is, all of the requirements of P3 in the NIH Guidelines (see Section II–B–3 of the Guidelines) will be followed, as well as certain of the additional requirements P4. Among these are II–B–4–a–9 (steam sterilization), II–B–4–a–13 and –14 (clothing change and shower), and II–B–4–c–1 (special laboratory design). Furthermore, the island location of Plum Island and the fact that the island is closed to the public adds an additional safety barrier.

The host-vector system to be used for the cloning of foot-and-mouth disease virus in this proposal is an EK1CV system, consisting of the host *E. coli* strain K–12 and the plasmid pBR322. This host-vector system satisfies the criterion of EK1CV, since pBR322 is a vector certified for use in an EK2 system. The EK1CV level of biological containment is higher than EK1. [See Decision Document accompanying NIH Guidelines in the **Federal Register** on December 22, 1978 (43 FR 60089).] The safety of the EK1 host-vestor system, and the extremely low probability of its use causing an adverse environmental impact, have been extensively analyzed previously. Analyses appear in the NIH Environmental Impact Statement on the 1976 Guidelines, in the report of the Falmouth meeting "Risk Assessment of Recombinant DNA Experimentation With *Escherichia coli* K–12" *[Journal of Infectious Diseases 137*, 615 (1978)], in the Environmental Impact Assessment accompanying proposed revised guidelines in the **Federal Register** on July 28, 1978 (43 FR 33042) and most recently, in the Decision Document/ Environmental Impact Assessment accompanying proposed revised guidelines in the **Federal Register** on November 30, 1979 (44 FR 69210). As discussed in the latter document, in order to cause a hazardous situation a series of steps must occur, each of which has a low probability; this results in an exceedingly low probability of harm. Analyzed in the latter document is the low probability of each of the following: significant escape of *E. coli* K–12 from a P1 laboratory (the work in this proposal will be done in a laboratory that exceeds the requirements of P3, thus making the probability of escape even lower than for a P1 laboratory); *E. coli* causing an epidemic by person-to-person spread; pathogenicity of *E. coli* K–12; *E. coli* K–12 being made pathogenic by the insertion of recombinant DNA; implantation of *E. coli* K–12 in the intestinal tract of laboratory animals or man; survival of *E. coli* K–12 carrying recombinant DNA; transfer of recombinant DNA *E. coli* K–12 to other organisms; and recombinant DNA in *E. coli* K–12 causing autoimmune disease.

Further, the specific hazards of cloning viral recombinant DNA in *E. coli* K–12 were the subject of the "U.S.-EMBO Workshop to Assess Risks For Recombinant DNA Experiments Involving The Genomes of Animal, Plant and Insert Viruses," held in Ascot, England, January 27–29, 1978. The report of this workshop, attended by American and European experts and published in the **Federal Register** both on March 31, 1978 (43 FR 13748) and on July 28, 1978 (43 FR 33159), concluded that "The probability that K–12 organisms carrying viral DNA inserts could represent a significant hazard to the community is so small as to be of no practical consequence. . . . Viral genomes or fragments thereof, cloned in *E. coli* K–12 using approved plasmid or phge vectors pose no more risk than work with the infectious virus or its nucleic acid and in most, if not all cases, clearly present less risk. In fact, the workshop participants agreed that cloning of viral DNA *E. coli* K–12 may provide a unique opportunity to study with greatly

reduced risks the biology of extremely pathogenic and virulent viruses."

I–D. *Amendment of Section I–D of the Guidelines*

The following notice appeared in the **Federal Register** on November 1, 1979: "The NIAID Risk-Assessment Working Group has proposed a major change to the NIH Recombinant DNA Guidelines that will broaden the field of investigations of risk assessment studies and will accelerate the process by which such studies will be carried out. At the present time, experiments allowable under the Guidelines are basically restricted to the use of DNA from non-pathogenic organisms which are propagated in host organisms that possess at least a moderate degree of biological containment. Experiments which involve genes for the biosynthesis of toxins potent for vertebrates, DNA from class 3, 4, and 5 pathogens, and DNA from plant pathogens that may increase virulence or host range are specifically prohibited by the Guidelines as are experiments which may involve 'wild type' host-vector systems: The design of risk assessment studies which now may be classified as allowable experiments may skew the studies toward negative results because of the absence of moieties which may confer hazardous qualities. Also, the results of such experiments may not allow extrapolation to assess risks of recombinant DNA experiments that may involve organisms which possess intrinsic hazardous qualities such as infectious microorganisms. On the other hand, it should be possible to measure more precisely the potential risk of recombinant DNA technology if experiments which fall within the prohibited categories were encouraged and carried out. While such experiments can be excepted from the prohibitions, the long process for granting exceptions discourages innovative research in the prohibited areas. The following major change is therefore recommended to encourage and stimulate relevant risk assessment studies that may lead to a more precise understanding of the potential hazards associated with recombinant DNA technology. The specific proposed change to the Guidelines is to add the following paragraph to the end of Section I–D: Experiments in Categories I–D–1, I–D–2, I–D–3, I–D–5, and experiments involving 'wild type' host-vector systems are excepted from the prohibitions provided that these experiments are designed for risk assessment purposes and are conducted within the NIH high containment facilities located in Building 41–T on the Bethesda campus and in Building 550 located at the Frederick Cancer Research Center. The selection of laboratory practices and containment equipment for such experiments shall be approved by ORDA following consultation with the RAC Risk Assessment Subcommittee and the NIH Biosafety Committee."

No comments were received during the 30-day comment period.

At the December 6–7, 1979, RAC meeting the importance of risk-assessment experiments was discussed. It was pointed out that acceptance of the proposed text to be added to the Guidelines could accelerate approval procedures for this class of risk-assessment experiments.

It was suggested that the text proposed for addition to the Guidelines be modified to delete reference to category I–D–5, i.e., experiments involving "deliberate transfer of a drug resistance trait . . ." On the other hand, a number of RAC members spoke of the importance of retaining category I–D–5 within the paragraph to be added, since valuable information might be learned about the mechanisms of antibiotic resistance. A motion to delete reference about category I–D–5 from the paragraph to be added to the Guidelines failed by a vote of 3 in favor, 13 opposed, with 3 abstentions.

In addition to the text to be added to the Guidelines as proposed in the **Federal Register** on November 1, 1979, additional text was suggested at the RAC meeting, dealing with notification of RAC members, and with destruction of clones.

At the conclusion of the discussion, the RAC recommended by a vote of 17 in favor, 1 opposed, with no abstentions that the following text be added at the end of Section I–D of the Guidelines:

"Experiments in Categories I–D–1, I–D–2, I–D–3, I–D–5, and experiments involving 'wild type' host-vector systems are excepted from the prohibitions, provided that these experiments are designed for risk-assessment purposes and are conducted within the NIH high containment facilities located in Building 41–T on the Bethesda campus and in Building 550 located at the Frederick Cancer Research Center. The selection of laboratory practices and containment equipment for such experiments shall be approved by ORDA following consultation with the RAC Risk-Assessment Subcommittee and the NIH Biosafety Committee. ORDA shall inform RAC members of the proposed risk-assessment projects at the same time it seeks consultation from the RAC Risk-Assessment Subcommittee and the NIH Biosafety Committee. If a major biohazard is determined, the clones will be destroyed after the completion of the experiment rather than retaining them in the high containment facility. Other clones that are non-hazardous or not of major hazard will be retained in the high containment.

I accept this recommendation and am today adding this text to the Guidelines.

The importance of risk-assessment experiments has been discussed previously in detail. [See "NIH Program to Assess the Risks of Recombinant DNA Research; Final Plan" (**Federal Register**, September 13, 1979)].

P4 physical containment consists of Laboratory Practices (Section II/B–4–a of the Guidelines), Containment Equipment (Section II–B–4–b of the Guidelines), and Special Laboratory Design (Section II–B–4–c of the Guidelines). The high containment facilities located in Building 41–T on the Bethesda campus and in Building 550 at the Frederick Cancer Research Center meet the P4 Special Laboratory Design requirements of Section II–B–4–c. (The great protection afforded by such P4 laboratory design is discussed in the Environmental Impact Statement on the 1976 Guidelines, and in the NIH Laboratory Safety Monograph.) For risk-assessment experiments to be conducted in these facilities, laboratory practices and containment procedures may be approved (by ORDA following a procedure specified above) which do not necessarily meet all the requirements of P4. ORDA will not approve selection of laboratory practices or containment equipment that presents a significant risk to health or the environment. The decision as to whether or not clones will be destroyed after completion of these experiments will be made by ORDA.

II. *Summary of Major Actions Under Guidelines*

II–A. *Amendment of Sections III–B–2, III–C–5, and III–C–6 of the Guidelines*

Sections III–B–2, III–C–5, and III–C–6 of the Guidelines are amended to change the words "* * * may be inserted into a lambdoid phage vector or into a vector from a certified EK2 host-vector system and propagated * * *" to "* * * may be inserted into a vector and propagated.* * *"

II—B. *Transfer of Cloned Segments of Anabaena DNA Into Klebsiella*

Permission is granted to transfer certain cloned segments of *Anabaena* DNA into *Klebsiella*, at P2 physical containment.

II–C. *Exception to Prohibition To Permit Cloning of Foot-and-Mouth Desease Virus in E. coli K–12*

Permission is granted to clone foot-and-mouth disease virus in the EK1CV host-vector system consisting of an *E. coli* K–12 and the vector pBR322, all work to be done at the Plum Island Animal Disease Center.

II–D. *Amendment of Section I–D of the Guidelines*

The following text is added at the end of Section I–D of the Guidelines: "Experiments in Categories I–D–1, I–D–2, I–D–3, I–D–5, and experiments involving 'wild type' host-vector systems are excepted from the prohibitions, provided that these experiments are designed for risk assessment purposes and are conducted within the NIH high-containment facilities located in Building 41–T on the Bethesda campus and in Building 550 located at the Frederick Cancer Research Center. The selection of laboratory practices and containment equipment for such experiments shall be approved by ORDA following consultation with the RAC Risk-Assessment Subcommittee and the NIH Biosafety Committee. ORDA shall inform RAC members of the proposed risk-assessment projects at the same time it seeks consultation from the RAC Risk-Assessment Subcommittee and the NIH Biosafety Committee. If a major biohazard is determined, the clones will be destroyed after the completion of the experiment rather than retaining them in the high containment facility. Other clones that are non-hazardous or not of major hazard will be retained in the high containment."

Additional Announcement of the Director, NIH

Section IV–E–1–b–(3)–(d) of the Guidelines gives responsibility to the Director, NIH, for "authorizing, under procedures specified by the RAC, large-scale experiments (i.e., involving more than 10 liters of culture) for recombinant DNAs that are rigorously characterized and free of harmful sequences."

On December 3, 1979, the Director, NIH, on the recommendation of the Recombinant DNA Advisory Committee, approved a request from Genentech, Inc., for the large-scale culture of EK1 host-vector systems carrying the chemically synthesized insulin A chain, insulin B chain, and the hormone somatostatin. The request was approved with the understanding that Genentech, Inc., has agreed to permit an observer, designated by NIH, to visit the facilities if NIH should choose to inspect the site.

The principal investigator is Dr. Brian, T. Sheehan. The work is to be done, as stipulated in the submission by Genentech, Inc., in a "P2 laboratory housing fermentors modified and tested to totally contain the recombinant organisms until they are chemically or physically killed at the end of each fermentation * * * at the research and development facility at 460 Point San Bruno Boulevard, South San Francisco, California 94080."

Dated: January 10, 1980.

Donald S. Fredrickson,

Director, National Institutes of Health.

[FR Doc. 80–1646 Filed 1–16–80; 8:45 am]

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