(4) Meta-Analysis and Combined Analysis Methodologies

Many of the cohorts at nuclear facilities are not individually large enough to detect statistically significant increases in mortality or incidence for rare cancer types. Methods and/or analyses for combining data across studies, whether in summary form or individual data, are valuable to the NIOSH research effort involving energy-related health research.

(5) Uncertainty Analysis

Measures of occupational exposure are inherently uncertain. Even when measures of external radiation exposure are generally available, the models, used to estimate organ dose, shallow versus deep dose, neutron dose, etc., are subject to error. Measures of dose derived from biological monitoring of urine, feces, blood, etc., are even less precise. Methods for assessing the degree of error in various estimates of exposure to both ionizing radiation as well as other toxic agents (chemicals, EMF, etc.) are desirable.

(6) Effects of Measurement Error on Risk Estimates

Estimation of both bias and imprecision introduced into risk analyses through exposure measurement error have recently received considerable attention. Many of the suggested approaches are very computer intensive. Practical solutions to this problem with regard to the spectrum of epidemiologic designs (cohort, casecontrol, cross-sectional, etc.) are needed, with particular attention to the nature of exposure measurement in radiation epidemiology.

(7) Studies of Current Workers

Much of the epidemiologic research on nuclear workers conducted at nuclear facilities and other sites has emphasized retrospective studies. More recently new activities involve environmental restoration, waste management and other work that is not related to the design and production of nuclear weapons. Workers are being exposed to radiation and other hazardous agents under conditions and in processes not previously encountered. Exposure assessment, epidemiologic and related studies are needed to evaluate these new conditions and processes and the impact on worker health.

Inclusion of Minorities and Women in Study Populations

Applicants are required to give added attention (where feasible and appropriate) to the inclusion of

minorities and/or women study populations for research into the etiology of diseases, research in behavioral and social sciences, clinical studies of treatment and treatment outcomes, research on the dynamics of health care and its impact on disease, and appropriate interventions for disease prevention and health promotion. Exceptions would be studies of diseases which exclusively affect males or where involvement of pregnant women may expose the fetus to undue risks. If minorities and/or women are not included in a given study, a clear rationale for their exclusion must be provided.

Evaluation Criteria

Upon receipt, applications will be reviewed for completeness and responsiveness by NIOSH. Incomplete applications will be returned to the applicant without further consideration. If NIOSH staff finds that the application is not responsive to this announcement, it will be returned without further consideration. If the proposed project involves organizations or persons other than those affiliated with the applicant organization, letters of suport and/or cooperation must be included.

Applications that are complete and responsive to this announcement will be evaluated for scientific and technical merit by an appropriate peer review group convened by the CDC in accordance with the review criteria stated below. As part of the initial merit review, a process (triage) may be used by the initial review group in which applications will be determined to be competitive or non-competitive based on their scientific merit relative to other applications received in response to this announcement. Applications judged to be competitive will be discussed and be assigned a priority score. Applications determined to be non-competitive will be withdrawn from further consideration and the principal investigator/program director and the official signing for the applicant organization will be promptly notified.

Review criteria for this announcement is the same as those for unsolicited research grant applications:

- Scientific, technical, or medical significance and originality of proposed research;
- —Appropriateness and adequacy of the experimental approach and methodology proposed to carry out the research;
- —Qualifications and research experience of the Principal Investigator and staff, particularly but exclusively in the area of the proposed research;

- Availability of resources necessary to perform the research;
- —Adequacy of plans to include both genders and minorities and their subgroups as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

The review group will critically examine the submitted budget and will recommend an appropriate budget and period of support for each scored application.

In the secondary (programmatic importance) review, the following factors will be considered:

- 1. Results of the initial review;
- 2. Magnitude of the problem in terms of numbers of workers affected;
- 3. Severity of the disease or injury in the worker population; and
- 4. Usefulness to applied technical knowledge in the identification, evaluation, and/or control of occupational safety and health hazards.

Applicants will compete for available funds with all other approved applications. The following will be considered in making funding decisions:

- 1. Quality of the proposed project as determined by peer review;
 - 2. Availability of funds; and
- 3. Program balance among research areas of the announcement.

Executive Order 12372—Review

Applications are not subject to the review requirements of Executive Order 12372, entitled Intergovernmental Review of Federal Programs.

Public Health System Reporting Requirement

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number is 93.262.

Other Requirements

Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations (45 CFR part 46) regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate