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James L. Liverman
Director, BER

SUPPORT OF BIOSTATISTICAL ACTIVITIES IN DESIGNATED LABORATORIES

I have recommended that statistical units at HNL, PNL and LASL be provided special funding at 30K, 55K and 50K respectively for the purposes to be discussed below. Since the 189 from Los Alamos did not arrive in sufficient time to be included in A and A consideration of the FY 1976 budget, I will request funding for LASL only for the 1977 budget submission. The principal purposes to be served by these specific 189's would be the following:

(a) to secure the availability of the services of personnel in these well organized and competent units to provide backup to BER staff on matters of current interest to us without interfering with their committed activities; and

(b) to have the groups conduct research and development on methodology appropriate to problems in the areas of analysis and assessment.

The following are some typical matters that require a greater effort than BER staff can expend and could be handled more rapidly and competently with the type of backup under consideration here:

1. Dr. Milham's statements that personnel at the Hanford plant are experiencing increased cancer incidence. This matter was referred to Battelle's statistical personnel who have received special funding of about $25,000 from the Richland Operations Office because of the great importance of these statements to the operation of the Hanford plant. Ordinarily, such funding is not available, and we are unable to carry out in-depth analyses of this type.

2. Dr. Drake's allegations regarding the Big Rock Point reactor.

3. Cochran's inquiry for NRDC regarding the statistical significance of increased cancer rates in Nevada.

4. The Lave and Seskin reports concerning increased mortality as a result of radiation and, separately, air pollution. The multiple regression techniques used by Lave are faulty as applied by him, but his results are quoted widely because they are either the only risk estimates available or the persons citing their results are not cognizant of the pitfalls in the use of these sophisticated techniques.

5. The calculations of expected leukemia and cancer deaths in the offspring of exposed females in the ERDA contractor population. The estimates were used in documents prepared by ERDA staff in the matter of the fertile female. The calculations for the estimates were made by the Division of Labor Relations. However, that division would have welcomed the more reliable assistance that we could have provided if the necessary backup were readily available.

Within the scope of the 189's, the following can be carried out by the statistical groups in addition to their BER backup activities:

1. Each group will consider the important issue of risk assessment under uncertainty. We have already and will in the future to an even greater extent calculate and use estimates of risk in terms of morbidity and mortality of exposed populations. The final calculations may be the result of a sequence of preliminary steps, each utilizing values that carry a measure of uncertainty. The implications of such estimates in terms of health and financial costs are so great that a program of examination of the statistical methodology used in estimation is clearly justified and should be made a specific mandate. Don Gardiner's group at Oak Ridge has been asked specifically to investigate this problem, but PNL and LASL have also been requested to consider it.

2. The statistical group at Battelle has been requested to investigate favorable methods for analysis of the data in such studies as the Health and Mortality Study and Dr. Milham's investigations. Their current activity in analyzing Milham's conclusions regarding cancer incidence has stimulated their interest in this problem, which they are willing to pursue in further methodologic investigations. Secondly, Battelle statisticians, especially Dr. Wesley Nicholson,

have on their own undertaken development of a new method, which they have named "catastrophe theory." If successful, it will provide an analytic mechanism for the representation of threshold effects. Robley Evans and Bob Rowland have asked Dr. Nicholson of the Battelle group to analyze their data from this standpoint, and he is currently cooperating with CHR personnel.

3. The Los Alamos statistical group has an interest in statistical aspects of non-linear dose-response relationships, which Ron Lohrding recognized as relevant to our program during his attendance at an A&E meeting at Argonne on May 8. In view of our recognition that a linear dose-response relationship is probably not appropriate for many biological effects due to low LET radiation, it is important to investigate the techniques for the representation of non-linear relationships. The LASL group would undertake their studies on appropriate bodies of data.

I favor special 189's to cover the above two classes of activities because the intervening layers of administration involved in funding under such programs as Regional Studies would, on the one hand, dilute the guidance from responsible BER staff and, on the other, diminish laboratory responsiveness to BER needs for backup on current, temporary issues.

(S)

Sidney Marks, M.D.
Analysis and Assessment Programs
Division of Biomedical and
Environmental Research

bcc: AAP rdg file

I disagree with this but would not object to funding PNL. GRRC has been funded - I hope that Gardner meeting SCK is for this purpose! JLR

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OFFICE	AAP	AAP	ADRDP	DD		
SURNAME	SMarks:ls	Swindbroad	Edington	Lvrr		
DATE	7/3/75	7/ /75	7/ /75	7/7/75		

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