



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

March 24, 1978

MEMORANDUM FOR: Karl R. Goller, Division of Siting, Health and
Safeguard Standards

FROM: David Rubinstein, Applied Statistics Branch

THRU: Roger H. Moore, Chief, Applied Statistics Branch
Stephen H. Hanauer, Office of the Executive Director *RAM*

SUBJECT: CONTRACTING FOR STUDIES ON HEALTH EFFECTS OF LOW
LEVEL IONIZING RADIATION

There is an obvious need for NRC to have the best up-to-date elucidation of the relationship between ionizing radiation and the incidence of cancer. In fact, the Office of Standards is currently working on an RFP for several "independent" short term studies on this subject. Below I shall briefly comment on these studies as well as suggest for your consideration two other studies. One would be similar to the currently proposed studies except it would provide NRC inputs into the methodology to be used and could be structured somewhat more flexibly. The other study would be long range and utilize considerable resources so that its results will be as definitive as practically possible. Much of the detail relating to these two studies is still tentative; the present intent is to identify possibly worthwhile objectives. The Applied Statistics Branch will be available for further discussion and support.

Current RFP Studies

The following comments given at this time are perhaps gratuitous; they are offered primarily for the record. Others and I have voiced objections or reservations about the current RFP (RS 050-78-011). None of these will be repeated here. Fairly intensive exchanges on the content of RFP have taken place up to yesterday (Thursday, March 23rd). Further refinement of the content would cause delay and probably not lead to any appreciable improvement in the contract work. Therefore, and because of the urgency perceived by your office of getting early results, it should go out as quickly as possible.

Quick Contract Study with NRC Inputs

If the premise of the RFP is valid, then it would seem desirable that NRC undertake an analysis of its own. Unfortunately, NRC may not have the resources to carry out such a study within the contemplated time frame of 3 months or so. An alternative is to contract out the analysis,

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but NRC staff would collaborate on the methods. For example, NRC could specify that among other methods the Haenzel-Mantel technique be used. In addition, the staff could specify the variables and intervals that define the cells in the Haenzel-Mantel technique. This would assure that the analysis will control for variables the NRC staff considers important. I would expect that most of the analytical initiative would come from the contractor. In any case, the precise relationship between contractor and NRC staff can be worked out if such a contract appears attractive and becomes a go proposition. This study would still have much of the limitations of the quick studies under RFP RS-OSD-78. However, there may be several advantages:

- (1) NRC has direct inputs.
- (2) Backup to "independent" studies should these turn out to be deficient or contradictory.
- (3) NRC gains experience in "direct" analysis of such data.
- (4) It will aid NRC in evaluating the studies done under the current RFP.
- (5) It could be made more flexible than the current RFP studies with respect to time limitations, data to be analysed, and (moderately) evolutionary analysis.

Most of these points do not need further comment except for (4). It is my understanding that current RFP is directed to analyses of the "same data" that Mancuso analysed. Under the "NRC" study one can deal with the data provided under the RFP or deal with the best (and most) data currently available. Possibly there could be two "NRC" studies so that each data set would be covered. If some of the analyses have been completed reasonably early, follow-up analyses can be devised to follow leads by these analyses or to clear up special problems.

Thorough Study

The elucidation of cancer etiology in natural populations under the influence of moderately inducing agents is a very difficult task. Among the difficulties are:

- (1) Number of cancers attributable to the agent are small.
- (2) Many factors influence cancer rates.

- (3) Strong heterogeneity within the population.
- (4) Limited data on the characteristics of the individual members.

Under these circumstances, it is almost hopeless to reach conclusive results with quick studies. The best hope (and this does not mean assurance) lies in a thorough study. Such a study should include the following features:

- (1) Preliminary survey of data. This includes tabulating and or plotting all variables of interest determining distributions and their parameters. This should be done univariately and to some extent multivariately; e.g. correlation matrix. This will serve two purposes:
 - (a) Deficiencies or peculiarities of the data will be revealed.
 - (b) It will provide a basis of structuring the data for analysis.
- (2) Whatever techniques the study may use, a prospective analysis should be a major part of it. In conjunction with the prospective analysis not only cancer rates would be investigated but also mortality in general.
- (3) As necessary the study will use sophisticated techniques to control for the many factors influencing cancer rates. Among the more simple ones is the Haenzel-Mantel method. There is practically no limit on the complexity of regression analyses. I use these here in the broad sense to include all curve fitting techniques such as those applied to the logistic model.
- (4) Such a study would use several perhaps somewhat redundant analyses to confirm the results obtained.
- (5) The study must be in part evolutionary. Suggested leads of the early analyses would be followed up and every reasonable attempt would be made to clarify peculiarities in the data.

The thorough study has by far the best prospect of serving NRC objectives.

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