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Comments for W. J. Bair,  
as requested.

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General Comments

The draft "Proposal for Accelerated Efforts", hereafter called the PROPOSAL, makes it clear that a study of health effects is currently proposed in addition to determination of "uptake and retention". Thus on p. 3 of the PROPOSAL it is said that "The principal goal of the expanded ... effort ... is ... to determine the impact ... on the health of ... residents." Again on p. 7: "Major emphasis in the expanded program will be on the medical follow-up ..."; and finally, p. 30, "... we must do all that is necessary ... to learn about any potential health effects ...".

Dr. Hall's letter of 2/25/66 can be read as foreshadowing this element of the PROPOSAL since he speaks of expanding "... our collaboration in the fields of health and safety." On the other hand Point 1 of the Annex to the letter, which more strictly defines the investigations being agreed to, specifies "Collection of information on uptake and retention ...".

It was clear at the meeting of 5/4/79 that Committee opinion varies on these points. The logic of opposition to a health study at this time is that if a preliminary determination of the level of internal contamination finds none,

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or a negligible quantity, further epidemiologic study would be vain.

There are other, less tangible, elements. Our principal collaborator and his agency are interested in the health of the residents; our counsel is sought on matters related to health and the study of health; and continuing discussion within the project has pursued the question of health for a long time.

Considering the whole background, my recommendation is to maintain and build upon the PROPOSAL with certain modifications and phasing adjustments detailed below.

#### Specific Recommendations

The PROPOSAL, I feel, is solidly based on the background and long-term realities of the situation. Recommendations are for a series of minor adjustments or improvements rather than any fundamental change. To begin with, I suggest the study be divided in two parts, as follows.

1. A study of uptake and retention as manifested by representative members of population groups potentially exposed.
2. A study of health effects in two phases:
  - a) a planning study to start now;
  - b) the actual investigation to start when, and if, significant levels are established in part 1.

1. Study of uptake and retention.

The PROPOSAL, while not entirely in accord with standard epidemiologic methodology, is I think well adjusted to the actual conditions in which the field work must be done. Hence I favor building upon the plan. The principal addition I would recommend, as a preliminary, is the development of a complete, stratified sampling frame before field work starts. This sampling frame, or list, of the affected population will systematize all existing information about such factors as age, sex, location of residence, occupation and potential exposure. One advantage in this particular case is that this listing can make full use of the other elements of study (ground area survey, animal sampling and particle-size determination, together with the earlier work in these three areas).

The function of such a sampling frame is to provide the necessary basis for design and implementation of an optimal stratified random sample for accurate determination of uptake and retention. The intent is to follow the main outline of the PROPOSAL requiring annual measurement of levels in small samples of approximately six subgroups of the population: once the frame is complete, any statistician on our collaborator's staff could design this sample readily. Subgroup samples would not turn out exactly 10, but can be kept small while still satisfying objectives. The most difficult element here is sampling randomly in the field: but this is worth insisting upon because of the scientific value of determinations made in this way.

In choosing the final subgroup sample sizes the statistician involved will need prior data on measurement variability and should be encouraged to apply U.S. results such as Moss et al (1969)\*.

2. Planning study of health effects.

There are several difficulties, inherent in the situation, which this planning phase is designed to meet. Epidemiologic methodology for study of chronic disease has developed quite rapidly since 1950 in England, the U.S. and a few other countries (e.g., Japan). Such methods have not been pursued in the location of interest, however. And in addition, the specific conditions of this study are not well suited to epidemiologic field work.

Our collaborator's interest in the health of residents and in "monitoring" leads, unfortunately, to the sort of anecdotal medical records well known to result in serious bias, which can be dangerously misleading. It would be my hope that by focussing substantial energy and attention, and some funds, on planning a modern epidemiologic survey, these anecdotal collections can be either avoided or counterbalanced.

An example concerns choice of controls for a health study (the control group in the PROPOSAL is adequate for a study of contamination levels) which can start in the planning phase. Step one is the choice of a "matched" or comparable community. Step two is recommended to be mere

\* Moss, W.D. et al. (1969). Health Physics 17, 571-8.

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recording of mortality in the two communities (without introducing new methods of data collection at this stage). Here the point is to be emphasized to our collaborator, that ascertainment of mortality must be identical in the exposed and control communities. That is, extra health care activities in the affected community, that might lead to finding deaths not otherwise recorded, must be balanced in the control community, or discounted. It is expected that such preliminary or planning investigations as an examination of mortality will have a beneficial educational effect in the circumstances.

No more need be said at this time about a later, actual study of health effects, except to mention that the sampling frame discussed above would provide the basis for the health study also (of course, a similar frame would require to be developed for any control population).

#### Summary of Recommendations

Controversy can be avoided by rewriting the proposal to separate: (i) determination of retention levels; (ii) planning for health studies not presently accessible or advisable; (iii) a possible future study of health.

The greater part of available funds and energy should be channeled to determination of accurate levels of internal contamination. Educational and preliminary planning activities to develop sufficient epidemiologic methodology for continuing, scientifically valid study of health, however, are fully justified.

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