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THE PROJECT ON CARCINOGENICITY
PROPOSED EPIDEMIOLOGICAL STUDIES

Objectives
Possible Approaches
Implementation

Preliminary Outline
for
The Subcommittee on Carcinogenicity
of the
API Medical Advisory Committee

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OBJECTIVES

- I. To determine as accurately as possible, the prevalence and incidence rates of retrograde, hypertrophic, and/or neoplastic responses in man following various degrees of exposure during production, processing, transportation and consumption to:-
 - A. petroleum products obtained by catalytic cracking processes.
 - B. petroleum products obtained by thermal cracking processes.
 - C. products encountered in wax extraction.
 - D. special chemical products.
 - E. various crude oils.
- II. To compare, insofar as possible, the prevalence and incidence rates found with similar rates of:-
 - A. groups of workers in the petroleum industry not directly in contact with petroleum or its products.
 - B. groups not employed in the petroleum industry, such as:-
 1. the general population
 - a. of the nation.
 - b. of the same geographic areas.
 2. the employees of other industries
 - a. of the nation.
 - b. of the same geographic areas.

III. To ascertain and evaluate, insofar as possible, the relative values of control procedures that are:-

- A. accepted and employed at the present time by essentially the entire industry.
- B. recommended but not adopted or employed except by a few companies.
- C. additional measures which may become important during the course of this investigation.

IV. To recommend for consideration of all interested parties, employing the results of the laboratory and epidemiological studies, standardized safety and control procedures provided that:-

- A. unusual incidence or prevalence rates are found justifying the control procedures..
- B. the measures increase the safety and efficiency of the operation even though the rates might not indicate a significant hazard.

POSSIBLE APPROACHES

I. Historical

Under this approach, the cooperating companies will forward to the University of Cincinnati all available clinical and employment records of proven or suspected cases of neoplastic disease which have been reported among their employees during the past insofar as records are available.

II. Current Registry

A. Clinical and Employment Record Study

A central registry will be established by the University of Cincinnati group to receive reports of neoplastic disease as they are discovered by and/or reported currently to the various Medical Departments. With this plan, the various cooperating companies would submit a fairly complete clinical report and an adequate employment record using standardized record forms. These records can be expected to be somewhat more reliable than those forwarded under the Historical Approach, since they would be completed immediately upon the report of a case.

B. Central Pathology Service

As an adjunct to the central registry, it would seem desirable to plan for the establishment of a central pathology service so that a uniform tissue diagnosis would be available both for the study purposes and to stimulate the interest and cooperation of the various Medical Departments.

III. Employee Health Record Study

In this investigation the epidemiological team of the University of Cincinnati would attempt a review of the employee health benefit records, not only of the various companies of the petroleum industry but certain other cooperating industries, to establish, insofar as possible, comparable incidence rates for all diseases. This approach, with due regard for the many variables, should develop certain useful intra- and extra-mural comparisons.

IV. Dermatological Field Study

This plan envisions field studies among various groups of workers employed not only in the petroleum industry but also in other industries with the objective of establishing comparable incidence rates for retrograde or hyperkeratotic lesions on the exposed skin surfaces. The groups to be surveyed by a trained team from the University of Cincinnati should be selected by an authorized committee familiar with all the possible variables and capable of securing adequate cooperation by all interested groups. These rates, if some degree of correlation is shown, could be used to determine susceptibility of individuals or groups, to estimate the degree of hazard in various situations and to evaluate control procedures that may be proposed.

V. Slack Wax Study

An investigation by one of the interested members of this group has pointed out an unusual hazard in their slack wax process. In view of this finding, it would be desirable for the survey group of the University of Cincinnati, working either independently or with some other company and/or companies, to repeat this investigation.