

Respondent	Number of respondents	Responses per respondent	Average No. hrs/tesponse
Director Follow-up	300	1	5/60

Dated: December 15, 2000.

Nancy Cheal,

Acting Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY-08-01]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

Thyroid Disease in Persons Exposed to Radioactive Fallout From Atomic Weapons Testing at the Nevada Test Site: Phase III—NEW—National Center for Environmental Health (NCEH), Centers for Disease Control and

Prevention (CDC). In 1997, the National Cancer Institute (NCI) released a report entitled, Estimated Exposures and Thyroid Doses Received by the American People from I-131 in Fallout Following Nevada Nuclear Bomb Test. This report provided county-level estimates of the potential radiation doses to the thyroid gland of American citizens resulting from atmospheric nuclear weapons testing at the Nevada Test Site (NTS) in the 1950's and 1960's. The Institute of Medicine (IOM) conducted a formal peer review of the report at the request of the Department of Health and Human Services. In the review, IOM noted that the public might desire an assessment of the potential health impact of nuclear weapons testing on American populations. The IOM also suggested that further studies of the Utah residents who have participated in previous studies of radiation exposure and thyroid disease might provide this information.

The National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC), proposes to conduct a study of the relation between exposure to radioactive fallout from atomic weapons testing and the occurrence of thyroid disease on an extension of a cohort study previously conducted by the University of Utah, Salt Lake City, Utah. This study is designed as a follow-up to a retrospective cohort study begun in 1965. This is the third examination (hence Phase III) of a cohort of individuals who were children living in Washington County, Utah, and Lincoln County, Nevada, in 1965 (Phase I) and

who were presumably exposed to fallout from above-ground nuclear weapons testing at the Nevada Test Site in the 1950s. The cohort also includes a control group who were children living in Graham County, Arizona, in 1966 and presumably unexposed to fallout.

The study headquarters will be at the University of Utah in Salt Lake City, Utah. The field teams will spend the majority of their time in the urban areas nearest the original counties if the same pattern of migration holds that was found in Phase II. These urban areas include St. George, Utah, the Wasatch Front in Utah, Las Vegas, Nevada, Phoenix/Tucson, Arizona, and Denver, Colorado. In addition, some time will be spent in California as a number of subjects had relocated there at the time of Phase II.

The purposes of Phase III are three fold: First to re-examine the participants in Phase II for occurrence of thyroid neoplasia and other diseases since 1986. Residents of the three counties who moved before they could be included in the original cohort will be located and examined. Second, disease incidence will be analyzed in addition to period prevalence as used in the Phase II analysis. Use of incidence will allow for greater power to detect increased risk of disease in the exposed population through the use of person-time. Third, disease specific mortality rates for Washington County, Utah, and a control county, Cache County, Utah, will be compared for people who lived in these two counties during the time of above-ground testing.

Respondents	Number of respondents	Responses/ respondent	Average burden response (hrs)
Telephone Location Script	4800	1	5/60
Telephone Location Script (Return Letter)	240	1	5/60
Refusal Telephone Script	48	1	5/60
New Person Location Telephone Script	2400	1	5/60
Recruitment Next of Kin Telephone Script	240	1	5/60
Questionnaire Not Returned Script #1 (New)	48	1	5/60
Questionnaire Not Returned Script #2 (New)	12	1	5/60
Recruitment & Appointment Script	4800	1	5/60
Broken Appointment Telephone Script	240	1	5/60
New Parent Recruitment & Appointment Script	120	1	5/60
New Parent Alternate Recruitment Script	60	1	5/60
Other New Parent Recruitment & Appointment	30	1	5/60
Other Parent or Relative Permissions Script	30	1	5/60
Exposure Questionnaire	2400	1	1
Questionnaire Preparation Booklet	2400	1	30/60
Group Member Information	4800	1	5/60
Consent Forms	4800	1	10/60

Respondents	Number of respondents	Responses/ respondent	Average burden response (hrs)
Interview Booklet	4800	1	30/60
Medical History Questionnaire (male)	2400	1	1
Medical Records Release Telephone Script	240	1	5/60
Medical History Questionnaire (female)	2400	1	1
Travel Form	480	1	20/60
Residence History	2400	1	5/60
Refusal Questionnaire	48	1	5/60

This comparison will determine if the risk of mortality in Washington County (the exposed group) is significantly greater than Cache County (the control group). CDC/NCEH is requesting a three-year clearance. The annual burden hours are estimated to be 13,607.

Dated: December 15, 2000.

Nancy Cheal,

Acting Associate Director for Policy, Planning, and Evaluation Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY-10-01]

Agency Forms Undergoing Paperwork Reduction Act Review

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information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

The Incidence of Breast and Other Cancers among Female Flight Attendants—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC)—Flight attendants experience exposures which may affect breast cancer risk including exposure to elevated levels of cosmic radiation and circadian rhythm disruption. This study will evaluate the incidence of breast and other cancers among a cohort of approximately 10,000

women who were employed as flight attendants.

The occurrence of breast and other cancers will be obtained from death certificates and from telephone interviews with living women and next-of-kin of deceased women. Each interview will take approximately 60 minutes to complete. Medical records will be requested to confirm cancer diagnoses. The primary analysis will evaluate the risk of breast and other cancers associated with occupational exposure within the cohort. The secondary analysis will compare the incidence of breast and other cancers in the cohort to that in the general population, with adjustment for factors which might increase cancer risk in the cohort independent of occupational exposure to cosmic radiation and circadian rhythm disruption. The annualized total burden is 10,525 hours.

Respondents	Number of respondents	Number of responses/ respondent	Avg. burden per response (in hrs.)
Flight attendants/proxies	10,000	1	60/60
Flight attendants/proxies whose eligibility for the study is unknown	300	1	5/60
Medical providers	1,000	1	30/60

Dated: December 15, 2000.

Nancy Cheal,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1637]

Agency Information Collection Activities; Proposed Collection; Comment Request; Transmittal of Advertising and Promotional Labeling for Drugs and Biologics for Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information regarding the promotion of prescription human drugs and biologics—specifically advertising and promotional labeling.