

Paperwork Reduction Act of 1995: Data collection requirements have been approved by the Office of Management and Budget (OMB) and are in effect, as required under the Paperwork Reduction Act of 1995 (OMB No. 0915-0272).

Executive Order 12372: The MCH Federal Set-Aside program has been determined to not be a program which is subject to the provisions of Executive Order 12372 concerning intergovernmental review of Federal programs.

Dated: November 28, 2003.

Elizabeth M. Duke,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Submission for OMB Review; Comment Request; Request for Generic Clearance To Collect Medical Outcome and Risk Factor Data From a Cohort of U.S. Radiologic Technologists

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on August 26, 2003, pages 51275-51276 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: *Title:* Request for Generic Clearance to Collect Medical Outcome and Risk Factor Data from a Cohort of U.S. Radiologic Technologists. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection (OMB No. 0925-0405 expired 09/30/1999). Need and Use of Information Collection. The primary aim of this project is to substantially increase knowledge about the long-term health affects associated

with protracted low- to moderate-dose radiation exposures. With this submission, the NIH, Office of Communications and Public Liaison, seeks to obtain OMB's generic approval to conduct occasional surveys of a cohort of U.S. radiologic technologist to ascertain incident cancers, benign conditions associated with high risk of cancer, and selected other health outcomes, as well as demographic, lifestyle, reproductive, employment, and other characteristics that may influence health risks. Researchers at the National Cancer Institute and the University of Minnesota have followed a nationwide cohort of 146,000 radiologic technologist since 1982, of whom 110,000 completed at least one of two prior questionnaire surveys and 17,000 are deceased. This cohort is unique because estimates of cumulative radiation dose to specific organs (e.g., breast) are available and the cohort is largely female, offering a rare opportunity to study effects of low-dose radiation exposure on breast and thyroid cancers, the two most sensitive organ sites for radiation carcinogenesis in women. Primary objectives are to quantify radiation dose-response for: (1) Cancers of the breast, thyroid, other radiogenic sites or histologies, and other cancers; (2) benign breast disease, thyroid nodules, and other benign conditions associated with increased cancer risk; and (3) other selected health outcomes that may be related to radiation exposure (e.g., cardiovascular disease). Findings from this study will address an important gap in the scientific understanding of radiation dose-rate affects, i.e., whether cumulative exposures of the same magnitude have the same health effects when received in single or a few doses over a very short period of time (as in atomic bomb or therapeutic exposures) or in many small doses over a protracted period of time (as in medical or nuclear occupational settings). The first survey will be mailed in 2004 to approximately 100,000 living cohort members who completed at least one prior survey and will collect information on: (1) Medical outcomes (as described above) to assess radiation-related risks; (2) detailed job-specific frequency of performing high-dose procedures (e.g., handling isotopes), use of protective measures (e.g., using lead aprons or standing behind shields), and other work practices (e.g., holding patients for x-rays) to refine the organ dose estimates and associated uncertainty distributions; and (3) behavioral, susceptibility, and residential histories for refining estimates of lifetime

ultraviolet (UV) radiation exposure to assess in greater detail the risks of melanoma and non-melanoma skin cancer associated with UV and ionizing radiation exposures, separately and jointly. Subsequent surveys will collect updated information on medical outcomes and risk factors of interest at that time. All surveys will be in optical-read format for computerized data capture. *Frequency of Response:* On occasion. *Affected Public:* U.S. radiologic technologists who have willingly participated in earlier investigations to quantify the carcinogenic risks of protracted low- to moderate-dose occupational radiation exposures. The annual reporting burden is as follows: *Estimated Number of Respondents:* 59,200. *Estimated Number of Responses Per Respondent:* 1. *Average Burden Hours per Response:* 0.4983. *Annual Burden Hours Requested:* 29,500. There are no capital costs, operating costs and/or maintenance costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Michele M. Doody, Radiation Epidemiology Branch, National Cancer Institute, Executive Plaza South, Room 7040, Bethesda, MD 20892-7238, or call non-toll-free at (301) 594-7203 or e-mail