

Dated: January 16, 1996.

Julia M. Fuller,

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).*

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## Agency for Toxic Substances and Diseases Registry

### Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Hanford Health Effects Subcommittee

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC) announce the following meeting.

*Name:* Citizens Advisory Committee on Public Health Service Activities and Research at DOE Sites: Hanford Health Effects Subcommittee (HHES).

*Times and Dates:* 8:30 a.m.-5 p.m., February 8, 1996; 7 p.m.-9 p.m., February 8, 1996; 9 a.m.-5 p.m., February 9, 1996.

*Place:* Marines' Memorial Club, 609 Sutter Street, San Francisco, California 94102, telephone 415/673-6672, FAX 415/441-3649.

*Status:* Open to the public, limited only by the space available. The meeting room accommodates approximately 150 people.

*Background:* A Memorandum of Understanding (MOU) was signed in October 1990 and renewed in November 1992 between ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or "Superfund"). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

In addition, under an MOU signed in December 1990 with DOE, the Department of Health and Human Services (HHS) has been given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially

exposed to radiation or to potential hazards from non-nuclear energy production and use. HHS delegated program responsibility to CDC.

*Purpose:* The purpose of this meeting is to receive an update from the Inter-tribal Council on Hanford Health Projects; brief on the status of the R-11 Survey; receive reports from the Outreach, Public Health Activities, and Health Studies Work Groups; and address other issues and topics, as necessary.

*Matters To Be Discussed:* The Subcommittee will consider a number of items including ATSDR's medical monitoring options, ATSDR's planning for a medical assistance program, and solicitation of concerns the Subcommittee wants ATSDR and CDC to address.

Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* Linda A. Carnes, Health Council Advisor, ATSDR, E-28, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/639-0730, FAX 404/639-0759.

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## Centers for Disease Control and Prevention

[INFO-96-08]

### Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639-3453.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and

clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Wilma Johnson, CDC Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

### Proposed Projects

1. Metropolitan Atlanta Birth Defect and Risk Factor Surveillance Program—(0920-0010)—Extension—Birth defects are the leading cause of infant mortality in the United States, and they cause a great deal of lifelong morbidity. One in 33 infants are born with a major birth defect. Occasionally, medications or environmental agents have been recognized as causes of birth defects, an example being the drug thalidomide in the early 1960s. Unless surveillance of trends and unusual patterns in birth defects is undertaken, new "thalidomides" may be introduced and fail to be recognized in a timely fashion. The Metropolitan Atlanta Congenital Defects Program (MACDP) has conducted such surveillance since 1967 using existing hospital and clinic medical records.

The causes of the majority of birth defects, however, are not known. Birth Defects Risk Factor Surveillance (BDRFS) (which began in January, 1993) attempts to find the causes of a selected subset of major anomalies, using an ongoing case-control study approach. BDRFS draws its cases from the data collected by MACDP and conducts in-depth interviews with the parents of affected infants and a comparison set of randomly selected parents of unaffected infants.

The objectives of these two activities are: (1) To conduct surveillance for congenital anomalies in metropolitan Atlanta; (2) to gain new information on causes of birth defects; (3) to further evaluate factors already suspected of influencing the occurrence of birth defects; and (4) to develop and test methods (including the use of biologic markers of exposure and susceptibility) in birth defect surveillance that would be exportable to other birth defects surveillance systems. The total cost to respondents is estimated at \$6,000.

Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hours.)	Total burden (in hours.)
BDRFS Parents Questionnaire .....	600	1	1	600
Total .....	.....	.....	.....	600

2. Case-Control Study of Infant Pulmonary Hemorrhage in the United States—New—The purpose of this proposed study is to conduct a nationwide case-control study to investigate the association between the presence of molds, particularly *Stachybotrys atra* (*S. atra*), in the home environment and the development of pulmonary hemorrhage in infants. From January 1993 to November 1994, a cluster of 18 infant pulmonary hemorrhage cases were identified in Cleveland, Ohio. An epidemiologic,

clinical, and laboratory investigation conducted by pediatric pulmonologists in Cleveland, the Ohio Department of Health (ODH), the City of Cleveland Department of Public Health (CDPH), the Cuyahoga County Board of Health (CCBH) with assistance from CDC, uncovered evidence that suggested an etiological role for environmental contaminants in the development of this disease. Of particular concern are trichothecene derivatives, which are potent mycotoxins produced by the fungus, *S. atra*. Trichothecene toxins

have been indicted as etiologic agents in hemorrhagic disorders in animals, but these compounds have not previously been associated with pulmonary hemorrhage in humans. Although the investigation in Cleveland produced evidence that exposure to toxin-laden spores from *S. atra* may be involved in the etiology of pediatric pulmonary hemorrhage, there is not yet sufficient data to indicate whether or not these mycotoxins are associated with pulmonary hemorrhage in other areas of the U.S. There is no cost to respondents.

Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hours)	Total burden (in hours)
Parents of a diagnosed infant (case) .....	30	1	1	30
Parents of a well infant (control) .....	30	1	1	30
Control recruitment telephone interview .....	15	1	.167	3
Total .....	.....	.....	.....	63

3. National Passive Surveillance for Invasive Group A Streptococcal Infections and the Streptococcal Toxic Shock Syndrome—(0920–0276)—Reinstatement—The frequency and severity of invasive group A streptococcal (GAS;*S.pyogenes*) infections has increased in the United States since the mid-1980s. In 1992, nationwide passive surveillance for invasive GAS infections was approved by OMB for a limited period and a 3-page paper surveillance form was sent to State and local health departments. Data obtained through surveillance was used to follow trends in serotype distribution; clinical data contributed to formulating the definition of the streptococcal toxic shock syndrome (STSS) and to investigating the pathogenesis this and other severe streptococcal syndromes such as necrotizing fasciitis.

In 1994, the Surveillance Committee of the Council of State and Territorial Epidemiologists (CSTE) met to discuss

changes in the National Public Health Surveillance System. It was proposed that invasive GAS infections and STSS be added to the list of reportable diseases. This proposal was approved by CSTE in the spring of 1995. The proposed surveillance method includes hospital laboratory based reporting of culture confirmed invasive GAS infections (i.e., infection associated with a GAS isolate from a normally sterile site) to the State or local health department with electronic transmission of data to CDC. Cases would be defined as having STSS based on a consensus definition published in 1993 by the Working Group on Severe Streptococcal Infections. Clinical data needed to establish whether STSS was present would be obtained from physicians or medical records and recorded electronically or on a 1-page paper form. Data from surveillance will be used to continue to monitor trends in disease occurrence, and to identify clusters of infection or other settings where public

health interventions may result in prevention of disease.

This system is likely to reduce the reporting burden compare with the previous approved surveillance in that the basic data collected on all cases includes only patient demographics, site of infection, clinical diagnosis, and outcome. Health departments, at their discretion, may also collect data needed to define a patient as having STSS, which includes obtaining data on seven clinical findings and can be recorded on a single page. Thus, both routine data collection and definition of STSS will require less time and effort than previously required to complete the 3-page reporting form. Electronic data transmission, through NETSS or a comparable system, will also facilitate reporting by States to CDC through an established and accepted system. The total cost to respondents is \$20,000, based on an average hourly salary for those who complete and submit the reports.

Respondents	Number of respondents	Number of responses/ respondent	Average burden per response	Total burden
State Health Departments .....	50	40	.5	1000
Total .....	.....	.....	.....	1000

4. National Nosocomial Infections Surveillance (NNIS) System—(0920–0012)—Extension—The National Nosocomial Infections Surveillance (NNIS) system is currently the only source for national data on nosocomial (hospital-associated) infections in the United States. It first began collecting data in 1970. It is a collaborative project between the Hospital Infections Program of the Centers for Disease Control and Prevention (CDC) and voluntarily participating hospitals in the United States. The goals of the system are to: (1) Develop comparative nosocomial infection rates that can be used by hospitals to assess quality of care, (2) describe the scope and magnitude,

including trends, of the nosocomial infection problem in the U.S., (3) identify risk factors associated with these infections, (4) assist hospitals in the effective use of surveillance data to improve the quality of patient care, and (5) conduct collaborative research studies. Data are collected using protocols developed by CDC that define the specific populations of patients at risk, risk factors, and outcomes. The decision about which component(s) to use is made by each hospital depending on its own needs for surveillance data. The data are collected by trained surveillance personnel, assisted by hospital personnel, and are entered into IDEAS, a surveillance software which

makes the data available for analysis at the hospital's convenience. The data are currently transmitted to CDC by floppy disk, then aggregated into a national database. During 1996, it will become possible for some hospitals to transmit the data to CDC through the NNIS telecommunications system. This system is expected to be used by all participating hospitals by 1997, resulting in reduced response time. NNIS methodology, which has been published, is the standard nosocomial infection surveillance methodology and is used at least in part by most U.S. hospitals. The total cost for respondents is estimated at \$11,395.

Respondents	Number of respondents	Number of responses/ respondent	Average burden/ response (in hours)	Total burden (in hours)
Hospitals .....	251	12	0.16	481
Total .....	.....	.....	.....	481

5. Emergency Epidemic Investigations—(0920–0008)—Extension—During most emergency situations, CDC specialists (epidemiologist, biostatisticians, laboratory specialists, etc.) work under the aegis of a State or local health

department. Usually such investigations are completed by the State or local government, with technical assistance from CDC. Occasionally, an investigation must be continued or is multistate or global. In these cases, CDC collects or sponsors the collection of

information from the public. This request, therefore, is for the extension of OMB approval to collect data in such emergency situation. There is no cost to the respondent.

Respondents	Number of respondents	Number of responses/ respondents	Average burden/ response (in hours)	Total burden (in hours)
General Public .....	16,550	1	0.31	5131

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[30DAY–05]

#### Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review, 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 Office on (404) 639–3453.

The following requests have been submitted for review since the enactment of the PRA of 1995 on December 5, 1995.

#### Proposed Project

1. End Stage Renal Disease Study—(0920–0011)—Reinstatement—Kidney disease is one of the priority health conditions ATSDR has identified for epidemiologic studies. Contaminants such as heavy metals and solvents are

commonly found at hazardous waste sites and have been linked to end-stage renal disease in occupational studies. A case-control study of end-stage renal disease and residential proximity to hazardous waste sites conducted in New York State under the previous clearance suggested an increased risk for this association. An expansion of this original study is now planned in California to determine whether these findings can be replicated. The cases of end-stage renal disease will be identified from the records of the Health Care Financing Administration. Controls will be recruited by random