because the Agency views these as non-controversial revisions and anticipates no adverse comments. A detailed rationale for the approval is set forth in the preamble to the direct final rule. If EPA receives no adverse comments, EPA will not take further action on this proposed rule. If EPA receives adverse comments, EPA will withdraw the direct final rule and it will not take effect. EPA will address all public comments in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing on or before November 6, 2002.

ADDRESSES: Written comments may be mailed to: Richard R. Long, Director, Air and Radiation Program, Mailcode 8P–AR, United States Environmental Protection Agency, Region VIII, 999 18th Street, Suite 300, Denver, Colorado 80202–2466.

Copies of the documents relevant to this action are available for public inspection during normal business hours at the following offices: United States Environmental Protection Agency, Region VIII, Air and Radiation Program, 999 18th Street, Suite 300, Denver, Colorado 80202–2466; and, Air and Radiation Docket and Information, Room B–108, United States Environmental Protection Agency, (Mail Code 6102T), 1301 Constitution Avenue NW, Washington, DC 20460.

Copies of the State documents relevant to this action are available for public inspection at: Montana Department of Environmental Quality, Planning, Prevention and Assistance Division, 1520 East 6th Avenue, Helena, Montana 59620.

FOR FURTHER INFORMATION CONTACT: Jeffrey Kimes, Air and Radiation Program, Mailcode 8P–AR, United States Environmental Protection Agency, Region VIII, 999 18th Street, Suite 300, Denver, Colorado 80202–2466. Telephone number: (303) 312–6445.

SUPPLEMENTARY INFORMATION: See the information provided in the Direct Final action of the same title which is located in the Rules and Regulations section of this **Federal Register**.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: September 12, 2002.

Jack McGraw,

Acting Regional Administrator, Region VIII.

[FR Doc. 02–25288 Filed 10–4–02; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 61

[ND–001–0005b & ND–001–0007b; FRL–7379–9]

Clean Air Act Approval and Promulgation of Air Quality Implementation Plan Revision for North Dakota; Revisions to the Air Pollution Control Rules; Delegation of Authority for New Source Performance Standards and National Emission Standards for Hazardous Air Pollutants

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule and delegation of authority.

SUMMARY: EPA proposes to approve revisions to the State Implementation Plan (SIP) submitted by the Governor of North Dakota with a letter dated June 21, 2001. The revisions affect air pollution control rules regarding general provisions, emissions of particulate matter and fugitives, exclusions from Title V permit to operate requirements, and prevention of significant deterioration. EPA will handle separately direct delegation requests for emission standards for hazardous air pollutants for source categories and the State's Acid Rain Program.

In addition, EPA is providing notice that on January 3, 2002, North Dakota was delegated authority to implement and enforce certain New Source Performance Standards (NSPS), as of August 1, 2000. Finally, given that on July 7, 1995 EPA delegated authority to North Dakota to implement and enforce the Clean Air Act section 112 requirements, including, among other things, the National Emission Standards for Hazardous Air Pollutants (NESHAPs), EPA proposes to remove the State's NESHAPs regulations from the federally-approved SIP.

In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial SIP revision and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this proposed rule, no further activity is contemplated in relation to this rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing on or before November 6, 2002.

ADDRESSES: Written comments may be mailed to Richard R. Long, Director, Air and Radiation Program, Mailcode 8P–AR, Environmental Protection Agency (EPA), Region VIII, 999 18th Street, Suite 300, Denver, Colorado 80202. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air and Radiation Program, Environmental Protection Agency, Region VIII, 999 18th Street, Suite 300, Denver, Colorado 80202. Copies of the State documents relevant to this action are available for public inspection at the North Dakota Department of Health, Division of Environmental Engineering, 1200 Missouri Avenue, Bismarck, North Dakota 58504–5264.

FOR FURTHER INFORMATION CONTACT: Amy Platt, EPA, Region VIII, (303) 312–6449.

SUPPLEMENTARY INFORMATION: See the information provided in the Direct Final action of the same title which is located in the Rules and Regulations section of this **Federal Register**.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: September 3, 2002.

Robert E. Roberts,

Regional Administrator, Region VIII.

[FR Doc. 02–25290 Filed 10–4–02; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 46

Proposed Waiver of the Applicability of Certain Provisions of Department of Health and Human Services Regulations for the Protection of Human Subjects for Department of Health and Human Services Epidemiologic Research Involving Prisoners as Subjects

AGENCY: Office for Human Research Protections, Office of Public Health and Science, Office of the Secretary, Department of Health and Human Services.

ACTION: Proposed notice of waiver.

SUMMARY: The Department of Health and Human Services (DHHS) is proposing to waive the applicability of certain provisions of Subpart C of 45 CFR part 46, the DHHS regulations for the protection of human subjects, to specific types of epidemiological research involving prisoners as subjects. Subpart

C, entitled Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects, sets forth specific requirements for any research involving prisoners that is conducted or supported by DHHS. Pursuant to 45 CFR 46.101(i), the Secretary of Health and Human Services proposes waiving the applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) to allow DHHS to conduct or support certain important and necessary epidemiologic research that presents no more than minimal risk and no more than inconvenience to prisoner-subjects.

DATES: Comments on the proposed waiver must be received on or before November 6, 2002.

ADDRESSES: Comments must be sent to: Irene Stith-Coleman, Ph.D., Office for Human Research Protections (OHRP), The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Telephone 301–496–7005. E-mail *istithco@osophs.dhhs.gov*. The Department invites written comments on the proposed waiver.

FOR FURTHER INFORMATION CONTACT: Irene Stith-Coleman, Ph.D., Office for Human Research Protections (OHRP), The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Telephone 301–496–7005. E-mail *istithco@osophs.dhhs.gov*. Interested persons may obtain a copy of the current regulations for protection of human subjects, including subpart C, at *http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm*.

SUPPLEMENTARY INFORMATION:

Proposed Waiver

Pursuant to 45 CFR 46.101(i), the Secretary of Health and Human Services (HHS) proposes waiving the applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain research conducted or supported by DHHS. In specific, for DHHS conducted or supported research involving epidemiologic studies (1) in which the sole purposes are (i) to describe the prevalence or incidence of a disease by identifying all cases, or (ii) to study potential risk factor associations for a disease, and (2) where the institution responsible for the conduct of the research certifies to the Office for Human Research Protections (OHRP), acting on behalf of the Secretary, that the Institutional Review Board (IRB) approved the research and fulfilled its duties under 45 CFR 46.305(a)(2)-(7) and determined and documented that (i) the research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and (ii) prisoners are not a particular focus of the research, the Secretary of DHHS proposes waiving the requirements in sections 46.305(a)(1) and 46.306(a)(2) that the IRB and the Secretary determine that the research involves one of the categories of research permissible under 45 CFR 46.306(a)(2).

Background

DHHS conducts or supports certain epidemiologic studies in which the purposes are: (1) to describe the prevalence or incidence of a disease by identifying all cases, and (2) to study potential risk factor associations for a disease. For most such studies, the IRB determines that the research at issue involves no more than minimal risk and no more than inconvenience to the subjects. The human participants in this type of public health research may include prisoners in the study population. State health agencies are most commonly the conduits for this kind of research.

Subpart C of the DHHS regulations, set forth in 45 CFR 46.301 *et seq.*, defines four categories of research that may involve prisoners. Sections 45 CFR 46.305(a)(1) and 46 306(a)(2) require that IRBs and the Secretary, respectively, determine that research involving prisoners represent one of these four categories. The first three, paragraphs (i), (ii), and (iii) of 46.306(a)(2), require that the research target either (i) the causes, effects, or processes of incarceration and of criminal behavior; (ii) the prison as an institution or prison life; or (iii) conditions particularly affecting prisoners as a class. The fourth, paragraph (iv) of 46.306(a)(2), permits research on practices which have the intent and reasonable probability of improving the health or well-being of the prisoner-subject. Certain epidemiologic studies conducted or supported by the DHHS do not fall into any of these four categories. Instead, the research focuses on a particular condition or disease which might affect prisoners as it would anyone else in the population.

An example of an epidemiological study that would be permitted under the proposed waiver is one in which all persons with HIV, but with none of the known risk factors for HIV, are asked to participate in a study involving an interview, review of medical records, and collection of a blood specimen. The purpose of the study is to determine other potential risk factors for HIV. All states with mandatory HIV reporting laws report these cases to the Centers for Disease Control and Prevention (CDC). Each person who meets the study definition would be asked to participate, and prisoners could well be members of the potential study group.

The range of studies to which the proposed waiver would apply includes chronic diseases, injuries, and environmental health. This type of research uses epidemiologic methods (such as interviews and collection of biologic specimens) that entails no more than minimal risk to the subjects.

The specific type of epidemiological research conducted by DHHS and subject to the proposed waiver involves no more than minimal risk and no more than inconvenience to the human subject participants. The proposed waiver would allow DHHS to conduct or support a type of minimal risk research that does not now fall within the categories set out in 45 CFR 46.306(a)(2).

Periodic Review

If implemented, a periodic review of the ways in which DHHS implements the proposed waiver would be conducted by OHRP to determine the adequacy of the waiver in meeting its intended need or if adjustments to the waiver might be necessary and appropriate.

Dated: September 9, 2002.

Eve E. Slater,

Assistant Secretary for Health.

Approved: September 26, 2002.

Tommy G. Thompson,

Secretary, Department of Health and Human Services.

[FR Doc. 02–25205 Filed 10–4–02; 8:45 am]

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