period and subsequent embryo extraction; and

(v) Ability of the device to permit oxygen and carbon dioxide exchange between the media contained within the device and the external environment throughout the vaginal incubation period.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the sterility of the device components intended to be provided sterile.

(5) Shelf life testing must demonstrate that the device maintains its performance characteristics and the packaging of device components labeled as sterile maintain integrity and sterility for the duration of the shelf life.

(6) Labeling for the device must include:

(i) A detailed summary of the clinical testing, including device effectiveness, device-related complications, and adverse events;

(ii) Validated methods and instructions for reprocessing of reusable components;

(iii) The maximum number of gametes or embryos that can be loaded into the device;

(iv) A warning that informs users that the embryo development is first evaluated following intravaginal culture; and

(v) A statement that instructs the user to use legally marketed assisted reproductive technology media that contain elements to mitigate the contamination risk (*e.g.,* antibiotics) and to support continued embryonic development over the intravaginal culture period.

(7) Patient labeling must be provided and must include:

(i) Relevant warnings, precautions, and adverse effects and complications;

(ii) Information on how to use the device;

(iii) The risks and benefits associated with the use of the device; and

(iv) A summary of the principal clinical device effectiveness results.

Dated: December 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–33264 Filed 1–5–16; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[EPA–R07–OAR–2015–0733; FRL–9941–06–Region 7]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants; Nebraska; Sewage Sludge Incinerators

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to approve the Clean Air Act (CAA) section 111(d)/129 negative declaration for the state of Nebraska, for existing sewage sludge incinerator (SSI) units. This negative declaration certifies that existing SSI units subject to sections 111(d) and 129 of the CAA do not exist within the jurisdiction of Nebraska. EPA is accepting the negative declaration in accordance with the requirements of the CAA.

DATES: This direct final rule will be effective March 7, 2016, without further notice, unless EPA receives adverse comment by February 5, 2016. If EPA receives adverse comment, we will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2015–0733, to *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Paula Higbee, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219 at 913–551–7028 or by email at *higbee.paula@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document ''we,'' ''us,'' or ''our'' refer to EPA. This section provides additional information by addressing the following:

I. Background

The CAA requires that state regulatory agencies implement the emission guidelines and compliance times using a state plan developed under sections 111(d) and 129 of the CAA. The general provisions for the submittal and approval of state plans are codified in 40 CFR part 60, subpart B and 40 CFR part 62, subpart A. Section 111(d) establishes general requirements and procedures on state plan submittals for the control of designated pollutants. Section 129 requires emission guidelines to be promulgated for all categories of solid waste incineration units, including SSI units. Section 129 mandates that all plan requirements be at least as protective and restrictive as the promulgated emission guidelines. This includes fixed final compliance dates, fixed compliance schedules, and Title V permitting requirements for all affected sources. Section 129 also requires that state plans be submitted to EPA within one year after EPA's promulgation of the emission guidelines and compliance times.

States have options other than submitting a state plan in order to fulfill their obligations under CAA sections 111(d) and 129. If a State does not have any existing Sewage Sludge Incineration (SSI) units for the relevant emissions guidelines, a letter can be submitted certifying that no such units exist within the State (*i.e.,* negative declaration) in lieu of a state plan. The negative declaration exempts the State from the requirements of subpart B that would otherwise require the submittal of a CAA section 111(d)/129 plan.

On March 21, 2011 (76 FR 15372), the EPA established emission guidelines and compliance times for existing SSI units. The emission guidelines and compliance times are codified at 40 CFR 60, Subpart MMMM. In order to fulfill obligations under CAA sections 111(d) and 129, NDEQ submitted a negative declaration letter to EPA on December 6, 2012. The submittal of this declaration exempts NDEQ from the requirement to

submit a state plan for existing SSI units.

II. Analysis of State Submittal

In this Direct Final action, EPA is amending part 62 to reflect receipt of the negative declaration letter from the NDEQ, certifying that there are no existing SSI units subject to 40 CFR part 60, subpart MMMM, in accordance with Section 111(d) of the CAA. If a designated facility (*i.e.,* existing SSI unit) is later found within NDEQ's jurisdiction after publication of this **Federal Register** action, then the overlooked facility will become subject to the requirements of the Federal plan for that designated facility, including the compliance schedule. The Federal plan will no longer apply, if we subsequently receive and approve the 111(d) plan from the jurisdiction with the overlooked facility. EPA is publishing this direct final rule without a prior proposed rule because we view this as a noncontroversial action and anticipate no adverse comment. However, in the ''Proposed Rules'' section of this **Federal Register**, we are publishing a separate document that will serve as the proposed rule to approve the negative declaration if adverse comments are received on this direct final rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. For further information about commenting on this rule, see the **ADDRESSES** section of this document. If EPA receives adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that this direct final rule will not take effect. We will address all public comments in any subsequent final rule based on the proposed rule.

III. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). This action is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal requirement, and does not alter the relationship or the distribution of power and responsibilities established in the Act. This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it approves a state rule implementing a Federal standard. In reviewing section 111(d)/129 plan submissions, EPA's role is to approve State choices, provided that they meet the criteria of the Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a section 111(d)/129 plan submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a section 111(d)/129 plan submission, to use VCS in place of a section 111(d)/129 plan submission that otherwise satisfies the provisions of the Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 7, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action approving Nebraska's section 111(d)/129 plan revision for SSI sources may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects in 40 CFR Part 62

Environmental protection, Air pollution control, Administrative practice and procedure, Intergovernmental relations, Reporting and recordkeeping requirements, Sewage sludge incinerators.

Dated: December 23, 2015.

Mark Hague,

Regional Administrator, Region 7.

For the reasons stated in the preamble, EPA amends 40 CFR part 62 as set forth below:

PART 62—APPROVAL AND PROMULGATION OF STATE PLANS FOR DESIGNATED FACILITIES AND POLLUTANTS

■ 1. The authority citation for part 62 continues to read as follows:

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

Subpart CC—Nebraska

* * * * *

■ 2. Subpart CC is amended by adding an undesignated center heading and § 62.6917 to read as follows:

Air Emissions Standards of Performance for New Sewage Sludge Incinerators

§ 62.6917 Identification of plan—negative declaration.

Letter from the Nebraska Department of Environmental Quality received December 6, 2012, certifying that there are no Sewage Sludge Incinerator units subject to 40 CFR part 60, subpart MMMM.

[FR Doc. 2015–33292 Filed 1–5–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 164

Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and the National Instant Criminal Background Check System (NICS)

AGENCY: Office for Civil Rights, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (HHS or ''the Department'') is issuing this final rule to modify the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule to expressly permit certain HIPAA covered entities to disclose to the National Instant Criminal Background Check System (NICS) the identities of individuals who are subject to a Federal ''mental health prohibitor'' that disqualifies them from shipping, transporting, possessing, or receiving a firearm. The NICS is a national system maintained by the Federal Bureau of Investigation (FBI) to conduct background checks on persons who may be disqualified from receiving firearms based on Federally prohibited categories or State law. Among the persons subject to the Federal mental health prohibitor established under the Gun Control Act of 1968 and implementing regulations issued by the Department of Justice (DOJ) are individuals who have been involuntarily committed to a mental institution; found incompetent to stand trial or not guilty by reason of insanity; or otherwise have been determined by a court, board, commission, or other lawful authority to be a danger to themselves or others or to lack the mental capacity to contract or manage their own affairs, as a result of marked subnormal intelligence or mental illness, incompetency, condition, or disease. Under this final rule, only covered entities with lawful authority to make the adjudications or commitment decisions that make individuals subject to the Federal mental health prohibitor, or that serve as repositories of information for NICS reporting purposes, are permitted to disclose the information needed for these purposes. The disclosure is restricted to limited demographic and certain other information needed for NICS purposes. The rule specifically prohibits the disclosure of diagnostic or clinical information, from medical records or other sources, and any mental health information beyond the indication that the individual is subject to the Federal mental health prohibitor.

DATES: *Effective date:* This final rule is effective on February 5, 2016.

FOR FURTHER INFORMATION CONTACT: Andra Wicks, 202–205–2292.

SUPPLEMENTARY INFORMATION:

I. Background

On January 16, 2013, President Barack Obama announced 23 executive actions aimed at curbing gun violence across the nation. Those actions include efforts by the Federal government to strengthen the national background check system, and a specific commitment to ''[a]ddress unnecessary legal barriers, particularly relating to the Health Insurance Portability and Accountability Act, that may prevent States from making information available to the background check system.'' The National Instant Criminal Background Check System (NICS) is the system used to determine whether a potential firearms recipient is statutorily prohibited from possessing or receiving a firearm. The Department proposed, and now finalizes, a modification to the HIPAA Privacy Rule to permit certain covered entities to disclose to the NICS the identities of persons who are not allowed to possess or receive a firearm because they are subject to the Federal mental health prohibitor.

The National Instant Criminal Background Check System (NICS)

The Brady Handgun Violence Prevention Act of 1993, Public Law 103–159 (Brady Gun Law), and its implementing regulations, are designed to prevent the transfer of firearms by licensed dealers to individuals who are not allowed to possess or receive them as a result of restrictions contained in either the Gun Control Act of 1968, as amended (Title 18, United States Code, Chapter 44), or State law. The Gun Control Act identifies several categories (known as ''prohibitors'') of individuals [1] who are prohibited from engaging in the shipment, transport, receipt, or possession of firearms, including convicted felons and fugitives. Most relevant for the purposes of this rule is the Federal mental health prohibitor, which, pursuant to Department of Justice (DOJ) regulations, applies to individuals who have been involuntarily committed to a mental institution, for reasons such as mental illness or drug use; [2] found incompetent to stand trial or not guilty by reason of insanity; or otherwise determined by a court, board, commission, or other lawful authority to be a danger to themselves or others or unable to manage their own affairs, as a result of marked subnormal intelligence, or mental illness, incompetency, condition, or disease.[3] [4]

The Brady Gun Law established the NICS to help enforce these prohibitions, as well as State law prohibitions on the possession or receipt of firearms.[5] The NICS Index, a database administered by the Federal Bureau of Investigation (FBI), collects and maintains certain identifying information about individuals who are subject to one or more Federal prohibitors and thus who are ineligible to purchase firearms. As of 2012, the NICS Index also contains information on persons who are subject to State law prohibitions on the possession or receipt of firearms.[6] The

[1] See 18 U.S.C. 922(g) and (n) and implementing regulations at 27 CFR 478.11 and 27 CFR 478.32.

[2] The regulation, at 27 CFR 478.11, defines ''Committed to a mental institution'' as a formal commitment to the institution by a court or other lawful authority. The term does not apply to a person voluntarily admitted to a mental institution or in a mental institution merely for observation.

[3] The term used in the statute is ''adjudicated as a mental defective. The term includes a finding of insanity in a criminal case, and a finding of incompetence to stand trial or a finding of not guilty by reason of lack of mental responsibility pursuant to the Uniform Code of Military Justice. 27 CFR 478.11.

[4] This rule refers to the involuntary commitments and other applicable adjudications as, collectively, ''adjudications that make an individual subject to the Federal mental health prohibitor.''

[5] See Public Law 103–159, 18 U.S.C. 921–925, and implementing regulations at 28 CFR 25.1 through 25.11 (establishing NICS information system specifications and processes) and 27 CFR part 478 (establishing requirements and prohibitions for commerce in firearms and ammunition, including requirements related to conducting NICS background checks); and 42 U.S.C. 3759(b) (allocating a percentage of certain DOJ funds for State reporting of NICS data).

[6] See Statement Before the Senate Judiciary Committee, Subcommittee on Crime and Terrorism at a hearing entitled, ''THE FIX GUN CHECKS ACT: BETTER STATE AND FEDERAL COMPLIANCE, SMARTER ENFORCEMENT'' (November 15, 2011), by David Cuthbertson, Assistant Director, Criminal Justice Information Services Division, Federal Bureau of Investigation. Testimony available at: *http://www.justice.gov/ola/testimony/112-1/11-15-11-fbi-cuthbertson-testimony-re-the-fix-gun-checks-*