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DEPARTMENT OF ENERGY

10 CFR Part 430

[Docket No. EERE-2013-BT-NOA-0047]

RIN 1904-AD08

Energy Conservation Program: Energy Conservation Standards for Certain Consumer Products

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule.

SUMMARY: The U.S. Department of Energy (DOE or the "Department") adopts into the Code of Federal Regulations the definitions for "through-the-wall central air conditioner" and "through-the-wall central air conditioning heat pump" that were established in section 5 of the American Energy Manufacturing Technical Corrections Act. This document also removes the standards for air conditioners that were superseded effective in 2006, and the now defunct references to the "throughthe-wall air conditioner and heat pump" product class, including the definition and standards.

DATES: The effective date of this rule is May 12, 2014.

FOR FURTHER INFORMATION CONTACT: Mr. Lucas Adin, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, EE–2J, 1000 Independence Avenue SW., Washington, DC, 20585–0121, 202–287–1317, email: Lucas.Adin@ee.doe.gov. Jennifer Tiedeman, U.S. Department of Energy, Office of the General Counsel, GC–71, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 287–6111. email: Jennifer.Tiedeman@hq.doe.gov.

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I. Background and Authority

The American Energy Manufacturing Technical Corrections Act (AEMTCA), Public Law 112-210, was signed into law on December 18, 2012. Among its provisions are amendments to Part B 1 of Title III of the Energy Policy and Conservation Act of 1975 (EPCA or "the Act") (42 U.S.C. 6291-6309, as codified), which provides for an energy conservation program for consumer products other than automobiles, and to Part C² of Title III of EPCA (42 U.S.C. 6311-6317, as codified), which provides for an energy conservation program for certain commercial and industrial equipment, similar to the one in Part B for consumer products.³ Some of the AEMTCA amendments to EPCA establish or modify certain energy conservation standards and related definitions, and make technical changes to the Act. Other AEMTCA amendments to EPCA prescribe criteria for the conduct of rulemakings to promulgate energy conservation standards for various consumer products and commercial and industrial equipment, or direct the Department of Energy (DOE) to undertake rulemakings under

II. Discussion

In today's final rule, DOE is adopting several changes to its regulations regarding certain types of residential central air conditioners, which DOE proposed in a notice published on December 20, 2013. 78 FR 77019. Specifically, DOE proposed to amend the Code of Federal Regulations (CFR) to include the definitions for "through-thewall central air conditioner" and "through-the-wall central air conditioning heat pump" that were prescribed by the AEMTCA. 42 U.S.C. 6295(d)(4)(A)(ii). DOE proposed to amend the language of its regulations in 10 CFR 430.2 to adopt these statutory definitions. Although the definitions for "through-the-wall central air conditioner" and "through-the-wall central air conditioning heat pump" are new, these through-the-wall ("TTW") products have been subject to standards since 2006.

The December 20, 2013 proposed rule also included a proposal to remove a variety of provisions from 10 CFR 430.32(c) that reference historical standards. Specifically, DOE proposed to remove paragraph (c)(1) which contains standards for certain products manufactured between 1992/1993 and 2006. DOE also proposed to amend its regulations in 10 CFR 430.32(c)(2) and (c)(3) to remove references to the "through-the-wall air conditioner and heat pump" product class, which applied to certain products manufactured prior to January 23, 2010. To avoid confusion with the new statutory definitions, DOE proposed to remove the "through-the-wall air conditioner and heat pump" product class definition currently in 10 CFR

Although DOE is removing the outdated standards for the TTW product classes, DOE wants to be clear that the TTW products (for which this rule is adding definitions) are currently subject to standards. As discussed in a May 23, 2002 final rule that adopted amended energy conservation standards for several classes of residential central air conditioners and heat pumps, DOE initially created a separate product class for TTW products. 67 FR 36368, 36397. DOE explained that it was adopting separate standards for TTW products based on its analysis of the design characteristics of these products. Id. However, DOE also identified a concern

¹For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

² For editorial reasons, upon codification in the U.S. Code, Part C was redesignated Part A–1.

³ All references to EPCA in this document refer to the statute as amended through the enactment of the AEMTCA.

that separate standards for TTW products could encourage purchasers of equipment covered by more stringent standards to shift to TTW products. To address this concern, DOE defined the TTW product class as applicable to products manufactured prior to January 23, 2010, and specified that TTW products manufactured on or after that date would have to comply with the standard for other space-constrained products. 67 FR 36368, 36402

This definition was retained in the August 17, 2004 technical amendment that addressed the ruling of the U.S. Court of Appeals for the Second Circuit, which affected the standards for splitsystem and single-package central air conditioners but did not affect the standards for space-constrained and TTW products. 69 FR 50997, 50998. Thus, the 2004 rule again specified that the TTW standards applied to products manufactured prior to January 23, 2010, and that TTW products manufactured on or after that date would be subject to the space-constrained product class. The 2004 rule also included a footnote to the standards table in 10 CFR 430.32(c)(2) to ensure that this limitation was clear. Id. Finally, in the June 27, 2011 direct final rule that amended the current energy efficiency standards for residential central air conditioners and heat pumps, DOE again affirmed the applicability of the TTW product class and amended the footnote to clarify the classification of TTW products. 76 FR 37408, 37446.

Having received no public comments on the proposals in the December 20, 2013 proposed rule, DOE is adopting the proposed changes described in this section. DOE notes that, while this final rule removes the references to the nowdefunct TTW product class standards, through-the-wall central air conditioners and through-the-wall central air conditioning heat pumps must be assigned to a product class based on the product's characteristics. Product class definitions can be found in 10 CFR 430.2 and 10 CFR part 430, subpart B, appendix M. DOE believes that most, if not all, of the historicallycharacterized "through-the-wall" products will be assigned to one of the space-constrained product classes.

III. Procedural Requirements

A. Review Under Executive Order 12866

Today's regulatory action is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993). Accordingly, this action was not subject to review under that Executive Order by the Office of

Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB).

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) requires preparation of an initial regulatory flexibility analysis for any rule that by law must be proposed for public comment, unless the agency certifies that the proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, "Proper Consideration of Small Entities in Agency Rulemaking," 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's Web site (http://

www.energy.gov/gc).

DOE reviewed the amendments in the December 20, 2013 proposed rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003, and tentatively concluded that the proposed rule, if adopted, would not have a significant impact on small manufacturers under the provisions of the Regulatory Flexibility Act. These amendments add new statutory definitions for currently regulated products and have no impact on the applicable standards. These amendments also remove outdated regulatory requirements and do not otherwise change the regulatory framework for consumer products or commercial and industrial equipment that is currently in place. DOE received no comments objecting to this conclusion. For these reasons, DOE concludes and certifies that the rule would not have a significant economic impact on a substantial number of small entities and has not prepared a regulatory flexibility analysis. DOE has transmitted the certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the SBA for review under 5 U.S.C. 605(b).

C. Review Under the Paperwork Reduction Act of 1995

Manufacturers of residential central air conditioners and heat pumps must certify to DOE that their products comply with any applicable energy conservation standards. In certifying compliance, manufacturers must test their products according to the DOE test

procedures for residential central air conditioners and heat pumps, including any amendments to these procedures. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment, including residential central air conditioners and heat pumps. (76 FR 12422 (March 7, 2011)) The collectionof-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (PRA). This requirement has been approved by OMB under OMB control number 1910-1400. Public reporting burden for the certification is estimated to average 20 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

D. Review Under the National Environmental Policy Act of 1969

Pursuant to the National Environmental Policy Act of 1969, DOE has determined that this rule is covered under the Categorical Exclusion found in DOE's National Environmental Policy Act regulations at paragraph A.6 of Appendix A to Subpart D, 10 CFR Part 1021, which applies to rulemakings that are strictly procedural. Therefore, DOE does not need to prepare an Environmental Assessment or **Environmental Impact Statement for** this rule.

E. Review Under Executive Order 13132

Executive Order 13132, "Federalism," imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have Federalism implications. 64 FR 43255 (August 10, 1999). The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have Federalism implications. On March 14, 2000, DOE published a

statement of policy describing the intergovernmental consultation process that it will follow in developing such regulations. 65 FR 13735. DOE examined this final rule and determined that it will not have a substantial direct effect 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. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of today's final rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297) No further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

Regarding the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform," 61 FR 4729 (Feb. 7, 1996), imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; (3) provide a clear legal standard for affected conduct rather than a general standard; and (4) promote simplification and burden reduction. Section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation specifies the following: (1) The preemptive effect, if any; (2) any effect on existing Federal law or regulation; (3) a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) the retroactive effect, if any; (5) definitions of key terms; and (6) other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in sections 3(a) and 3(b) to determine whether they are met or whether it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this final rule meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4; 2 U.S.C. 1501 *et seq.*) requires each Federal agency to assess the effects of Federal regulatory actions on State,

local, and Tribal governments and the private sector. For a regulatory action resulting in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of \$100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish estimates of the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a)-(b)) UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed "significant intergovernmental mandate," and requires an agency plan for giving notice and opportunity for timely input to potentially-affected small governments before establishing any requirements that might significantly or uniquely affect such governments. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. (The policy is also available at www.energy.gov/gc). Today's final rule contains neither an intergovernmental mandate nor a mandate that may result in an expenditure of \$100 million or more in any year, so these requirements do not apply.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. Today's final rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

DOE has determined, under Executive Order 12630, "Governmental Actions and Interference with Constitutionally Protected Property Rights," 53 FR 8859 (March 18, 1988), that this regulation would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed today's final rule under OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use," 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OIRA a Statement of Energy Effects for any significant energy action. A "significant energy action" is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule and that (1)(i) is a significant regulatory action under Executive Order 12866, or any successor order; and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) is designated by the Administrator of OIRA as a significant energy action. For any significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use if the regulation is implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use. Today's regulatory action is not a significant regulatory action under Executive Order 12866. It has likewise not been designated as a significant energy action by the Administrator of OIRA. Moreover, it would not have a significant adverse effect on the supply, distribution, or use of energy. Therefore, it is not a significant energy action, and, accordingly, DOE has not prepared a Statement of Energy Effects.

L. Review Under Section 32 of the Federal Energy Administration Act of 1974

Under section 301 of the DOE Organization Act (Pub. L. 95–91; 42 U.S.C. 7101 et seq.), DOE must comply with section 32 of the Federal Energy Administration Act of 1974, as amended by the Federal Energy Administration Authorization Act of 1977 (FEAA). (15 U.S.C. 788) Section 32 essentially provides in part that, where a rule authorizes or requires use of commercial standards, the rulemaking must inform the public of the use and background of such standards. In addition, section 32(c) requires DOE to consult with the

Attorney General and the Chairman of the Federal Trade Commission (FTC) concerning the impact of the commercial or industry standards on competition.

The modifications to regulatory definitions addressed by this action do not incorporate testing methods contained in any new commercial standards not already referenced by the test procedures.

IV. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of today's final rule.

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Energy conservation, Household appliances.

Issued in Washington, DC, on April 7, 2014.

David T. Danielson.

Assistant Secretary, Energy Efficiency and Renewable Energy.

For the reasons stated in the preamble, DOE amends part 430 of chapter II, subchapter D, of title 10, of the Code of Federal Regulations, as set forth below:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 1. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 2. Section 430.2 is amended by removing the definition of "through-the-wall air conditioner and heat pump" and by adding, in alphabetical order, definitions for "through-the-wall central air conditioner" and "through-the-wall central air conditioning heat pump" to read as follows:

§ 430.2 Definitions.

* * * * *

Through-the-wall central air conditioner means a central air conditioner that is designed to be installed totally or partially within a fixed-size opening in an exterior wall, and:

- (1) Is not weatherized;
- (2) Is clearly and permanently marked for installation only through an exterior wall:
- (3) Has a rated cooling capacity no greater than 30,000 Btu/hr;
- (4) Exchanges all of its outdoor air across a single surface of the equipment cabinet; and
- (5) Has a combined outdoor air exchange area of less than 800 square

inches (split systems) or less than 1,210 square inches (single packaged systems) as measured on the surface described in paragraph (4) of this definition.

Through-the-wall central air conditioning heat pump means a heat pump that is designed to be installed totally or partially within a fixed-size opening in an exterior wall, and:

(1) Is not weatherized;

- (2) Is clearly and permanently marked for installation only through an exterior wall:
- (3) Has a rated cooling capacity no greater than 30,000 Btu/hr;
- (4) Exchanges all of its outdoor air across a single surface of the equipment cabinet; and
- (5) Has a combined outdoor air exchange area of less than 800 square inches (split systems) or less than 1,210 square inches (single packaged systems) as measured on the surface described in paragraph (4) of this definition.
- 3. Section 430.32 is amended by:
- a. Revising the introductory text to paragraph (c);
- b. Removing paragraph (c)(1);
- c. Redesignating paragraphs (c)(2) through (c)(6) as (c)(1) through (c)(5) respectively;
- d. Removing footnote 1 to the table in newly redesignated paragraph (c)(1);
- e. Removing newly redesignated paragraphs (c)(1)(v)(A) and (v)(B);
- f. Further redesignating newly redesignated paragraph (c)(1)(vi) as paragraph (c)(1)(v);
- g. Further redesignating newly redesignated paragraphs (c)(1)(vii)(A) and (vii)(B) as paragraphs (c)(1)(vi)(A) and (vi)(B) respectively;
- h. Removing footnote 1 to the table in newly redesignated paragraph (c)(2);
- i. Amending newly redesignated paragraph (c)(3) by removing the reference to "(c)(3)" and adding in its place "(c)(2)"; and
- j. Amending newly redesignated paragraph (c)(4), by removing the references to "(c)(3)" in both places and adding in their places, "(c)(2)".

The revision reads as follows:

§ 430.32 Energy and water conservation standards and their compliance dates.

(c) Central air conditioners and heat pumps. The energy conservation standards defined in terms of the heating seasonal performance factor are based on Region IV, the minimum standardized design heating requirement, and the sampling plan

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stated in § 429.16 of this chapter.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. FDA-2014-N-0355]

Advisory Committee: Bone, Reproductive and Urologic Drugs Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the standing advisory committees' regulations to change the name and function of the Advisory Committee for Reproductive Health Drugs. This action is being taken to reflect changes made to the charter for this advisory committee.

DATES: This rule is effective April 11, 2014.

FOR FURTHER INFORMATION CONTACT:

Teresa Hays, Committee Management Officer, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–8220.

SUPPLEMENTARY INFORMATION: FDA is announcing that the name of the Advisory Committee for Reproductive Health Drugs, which was established on March 23, 1978, has been changed. The Agency decided that the name "Bone, Reproductive and Urologic Drugs Advisory Committee" more accurately describes the subject areas for which the committee is responsible. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drug products for use in the practice of osteoporosis and metabolic bone disease, obstetrics, gynecology, urology and related specialties, and makes appropriate recommendations to the Commissioner of Food and Drugs.

The Bone, Reproductive and Urologic Drugs Advisory Committee name was changed and its functions expanded in the charter renewal dated March 23, 2014. In this final rule, FDA is revising 21 CFR 14.100(c)(9) to reflect these changes.

Publication of this final rule constitutes a final action on this change under the Administrative Procedure Act. Under 5 U.S.C. 553(b)(B) and (d) and 21 CFR 10.40(d) and (e), the Agency finds good cause to dispense with notice and public procedure and to proceed to an immediately effective regulation. Such notice and procedures are unnecessary and are not in the public