*The original of this document contains information which is subject to withholding from disclosure under 5 U.S. C. § 552. Such material has been deleted from this copy and replaced with XXXXXX's.

United States Department of Energy
Office of Hearings and Appeals

In the Matter of:		
Siemens Medical Solutions USA Inc.	)	
Siemens Healthcare Diagnostics Inc.	)	Case No.: EXC-16-0012
	)	
Filing Date: May 31, 2016	)	
	)	

Issued: November 9, 2016

Decision and Order

This Decision and Order considers an Application for Exception filed on May 31, 2016, by Siemens Medical Solutions USA Inc. and Siemens Healthcare Diagnostics Inc. (Siemens) seeking relief from the applicable provisions of the Energy Conservation Program: Energy Conservation Standards for Commercial and Industrial Electric Motors (Electric Motor Efficiency Standards or Final Rule), published on May 29, 2014, 79 Fed. Reg. 30934, and codified at 10 C.F.R. Part 431.[1] Compliance with the new Electric Motor Efficiency Standards was required as of June 1, 2016. Siemens asserts that it will face a serious hardship, gross inequity and an unfair distribution of burdens if required to comply with the Final Rule as applied to electric motors utilized in diagnostic medical equipment manufactured by Siemens. As set forth in this Decision and Order, we have concluded that Siemens' Application for Exception[2] should be granted.

[1] Upon receiving Siemens' Application, we advised Siemens that, before we could proceed with our evaluation of its request, the firm must: (1) correct a procedural deficiency relating to service upon "potentially aggrieved parties," 10 C.F.R. § 1003.23(a), and (2) clarify whether the firm was eligible to receive exception relief as an importer (and thus "a manufacturer", see 42 U.S.C. § 6291(10)) of electric motors. June 3, 2016, Letter from Fred L. Brown, Deputy Director, OHA, to Hans Beinke, Siemens. Siemens corrected the procedural deficiency and provided the requested clarifying information in supplemental submissions dated June 9, June 17 and June 22, 2016.

[2] Siemens also filed an Application for Stay concurrently with its Application for Exception. On July 5, 2016, we issued a decision granting Siemens' request and stayed the June 1, 2016, compliance date of the Electric Motor

I. Background

A. Electric Motor Efficiency Standards

Title III of the Energy Policy and Conservation Act of 1975, Public Law 94-163 (42 U.S.C. 6291 *et seq*.) (EPCA) initiated a variety of measures designed to improve energy efficiency of certain products. The Energy Policy Act of 1992, Pub. L. 102-486, amended EPCA to establish energy efficiency standards for some types of commercial and industrial equipment, including certain electric motors. The energy efficiency standards for electric motors, written directly into the Act, came into effect five years later, on October 24, 1997. Pub. L. 1-486, Sec. 122(b).

In 2007, Congress enacted the Energy Independence and Security Act of 2007 (EISA), Public Law 110-140, which amended the EPCA by updating the energy conservation standards for those electric motors already covered by the EPCA and established energy conservation standards for a larger scope of electric motors not already covered by standards. *See* 42 U.S.C. § 6313(b)(2) (codifying specific standards prescribed by Section 313(b) of EISA for general purpose electric motors (Subtypes I and II), fire pump motors, and NEMA Design B general purpose electric motors). Additionally, Congress further amended the EPCA by providing DOE with the explicit authority to establish regulatory coverage over "other motors" that fall outside of one of these prescribed motor types. *See* American Energy Manufacturing Technical Corrections Act, Pub. L. 112-210, Section 10(c) (December 18, 2012). Consistent with these legislative provisions, the DOE issued the Electric Motor Efficiency Standards in which it raised the efficiency standards for some electric motors, but more significantly, applied "the standards currently in place to a wider scope of motors that DOE does not [currently] regulate." 79 Fed. Reg. 30934, 30935 (May 29, 2014). Particularly relevant to the present proceeding, the Final Rule extended energy efficiency standards to certain general purpose motors that were previously not subject to regulation. *See* 10 C.F.R. § 431.25.

B. The Application for Exception

Siemens is a leading manufacturer and service provider for medical imaging and in-vitro diagnostic products (e.g. magnetic resonance imaging (MRI) machines and computed tomography (CT) equipment). In order to operate, in many instances these products utilize general purpose motors that were previously not covered by DOE efficiency standards but have now been made subject to regulation under the Final Rule. Siemens itself does not produce electric motors. However, Siemens not only sells new medical equipment containing covered motors to its customers, which are primarily healthcare institutions, but also services previously sold equipment which may involve replacing an electric motor as part of its repair. Siemens explains:

Efficiency Standards until OHA reached a decision on the present Application for Exception. *Siemens Medical Solutions USA Inc./Siemens Healthcare Diagnostics Inc.*, OHA Case No. EXS-16-0012 (July 5, 2016).

> We are not producers of electric motors. We do incorporate electric motors supplied by others in our medical imaging equipment (e.g. magnetic resonance (MRI) machines, computed tomography (CT) equipment, and position emission tomography (PET) equipment, and in-vitro diagnostic equipment. . . . Parts of the equipment are manufactured internationally, and when the new equipment is either manufactured domestically or imported with motors installed, the DOE's electric motor standards rule is triggered. We also provide ongoing service, maintenance and repair to healthcare providers and institutions with respect to the equipment we have sold to them. In some cases, it is necessary for us to replace a motor as part of a repair of the medical equipment. The replacement motor that is approved for use with our medical devices can come from overseas, and therefore each import triggers compliance with the DOE electric motor rule just like a motor manufactured domestically in the U.S.

Siemens' Application for Exception at 2.

Thus, Siemens requests relief from the Final Rule with respect to electric motors installed in new medical imaging and in-vitro diagnostic medical devices produced by the firm, as well as for replacement electric motors that Siemens installs in repairing existing medical devices.[3] Siemens contends that the firm, its customers and patients of its customers will suffer a serious hardship and gross inequity in the absence of relief. In this regard, Siemens states that medical imaging devices are heavily regulated by the U.S. Food & Drug Administration (FDA) which requires design verification and performance validation for all components, including electric motors, comprising these devices. S*ee* Siemens' Application for Exception at 2-3. Siemens asserts that it will be impossible for the firm to provide new medical devices housing compliant electric motors, or to replace all damaged or impaired electric motors in medical equipment in a timely way, because of the extensive testing, verification and validation of the use of compliant electric motors required by FDA regulations.

In further support of its exception request, Siemens submits that "the number of covered electric motors embraced by our application is not large." Siemens Application for Exception at 3. While Siemens could not precisely project the number of new and replacement motors the firm's customers will require during the pendency of its Application for Exception, Siemens attached to its Application a listing of the type and number of electric motors that it supplied in either new diagnostic devices or as replacement motors during XXXX. Siemens Application, Appendix A.

[3] In its initial Application for Exception, Siemens asserted that the firm required additional time to assess the impact of the Electric Motor Efficiency Standards upon its business and to determine its path toward compliance. Siemens requested that the firm be granted thirty days to supplement its Application with more precise information about its regulatory logistical challenges and a timeline for compliance with the Final Rule. Siemens Application for Exception at 3-4. On June 30, 2016, Siemens filed a Supplement to Application for Exception (Application Supplement) which describes Siemens' intended path forward toward compliance, discussed below.

Siemens approximated that, during XXX XXX XXX, the firm sold XXX motors (in new equipment or as a replacement) that would be subject to regulation under the Final Rule.[4] *Id.*

Additional information provided by Siemens,[5] however, has clarified that Siemens is not the "manufacturer" and thus has no standing to request exception relief with respect to many of these motors.[6] On June 22, 2016, Siemens submitted supplemental information in response to our June 3, 2016, letter stating: "Siemens is the official importer of record and can provide verifying U.S. Customs documentation for the MR (Magnetic Resonance) and CT (Computed Tomography) devices and replacement motors. The IVD (In Vitro Diagnostic) devices are not imported. The [IVD] motors are imported but we are not the official importer of record." June 22, 2016, Email from Hans Beinke, Siemens, to Fred L. Brown, Deputy Director, OHA. The revised Appendix A attached to Siemens' Application Supplement shows that new MRI and CT devices and replacement motors comprise only XX (XX%) of the XX electric motors sold by the firm in 2015 that would be now subject to regulation. Application Supplement, Appendix A, Table of Affected Motors and Proposed Conformance Deadlines (Amended). The remaining XXX motors are contained in IVD (In Vitro Diagnostic) devices for which Siemens is not the importer of record. *See id.* We emphasize that it is only with respect to the MRI and CT electric motors that Siemens is the "manufacturer" (as the importer of record) and therefore has standing to request exception relief. Thus, our consideration of Siemens' Application for Exception, set forth below, pertains only to the MRI and CT electric motors sold by Siemens.

In its June 30, 2016, Application Supplement, Siemens provided more specific information regarding its timetable for bringing its covered products into compliance with the new Electric Motor Efficiency Standards. According to Siemens, this will involve a three-step process: first, its electric motor suppliers must redesign their motors and subassemblies, and second and third,

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[4] In its supplemental submission of June 17, 2016, Siemens reduced this number (XXX) by XX to XX motors, stating that "[u]pon further investigation, we no longer need an exception to the motors contained in our XXXXXX device." Finally, in its Application Supplement, Siemens further reduced the number of affected motors from XXX to XXX, comprised of XX motors in CT devices, XX motors in MRI devices, and XXX motors in IVD (In Vitro Diagnostic) devices.

[5] See notes 1 and 3, *supra*.

[6] In our letter acknowledging receipt of Siemens' Application, we explained that OHA has authority to grant exception relief to manufacturers of electric motors distributed for sale in U.S. commerce to the extent a manufacturer is able to show that it will suffer a gross inequity, serious hardship or unfair distribution of burdens as a result of its compliance with the revised DOE energy efficiency standard of the Final Rule. *See* 10 C.F.R. Part 1003, Subpart B; Department of Energy Organization Act, 42 U.S.C. § 7194. As noted above, Siemens states in its Application for Exception that the firm itself is not a producer of electric motors. However, the Energy Policy and Conservation Act of 1975 (EPCA), 42 U.S.C. §§ 6291 *et seq*., pursuant to which the Electric Motor Efficiency Standards were promulgated, defines "manufacturer" as "any person who manufactures industrial equipment" and defines "manufacture" as to "manufacture, produce, assemble, or import." *See* 42 U.S.C. § 6311(5) and (7); 42 U.S.C. § 6291(10). We therefore requested that Siemens provide additional information clarifying whether the electric motors supplied by Siemens, contained in new equipment or as replacement motors, are: 1) produced domestically by other firms, 2) produced overseas and Siemens is the importer of record, and 3) produced overseas but Siemens is not the importer of record. June 3, 2016, Letter from Fred L. Brown, Deputy Director, OHA, to Hans Beinke, Siemens.

Siemens must perform design verification and performance validation in accordance with FDA standards. *See* Application Supplement at 1. According to Siemens, the first step could take from XXXX XXX XXX, while the FDA process will take approximately XXXX XXX. *Id.* Appendix A of the Application Supplement shows that Siemens projects a compliance date of XXX XXX, for its covered CT devices, and projects a compliance date of XXX XXX, for its covered MRI devices. *See* Application Supplement, Appendix A, Table of Affected Motors and Proposed Conformance Deadlines (Amended).

On July 29, 2016, we requested additional information relevant to our evaluation of Siemens' Application for Exception, as well as a status update regarding Siemens' compliance efforts. July 29, 2016, Letter from Fred L. Brown, Deputy Director, OHA, to Hans Beinke, Siemens. On September 20, 2016, Siemens provided such additional information and revised its projected timetable for bringing its covered MRI and CT devices into compliance. Siemens now projects a XXX XXX XXX, compliance date for its covered CT devices, and a XXXX XXXX, compliance date for its covered MRI devices. *See* Siemens' September 20, 2016, Submission (Final Supplement) at 1.

C. Comments

OHA received comments from two interested parties regarding Siemens' Application for Exception: (1) joint comments filed the American Council for an Energy Efficient Economy, the Appliance Standards Awareness Project, Earthjustice, and the Motors and Generators Section of the National Electrical Manufacturers Association (collectively, the "Joint Commenters"), and (2) the National Electrical Manufacturers Association (NEMA), a trade association whose members include manufacturers of electric motors. Letter from Joint Commenters to OHA (June 16, 2016); Letter from NEMA to Fred Brown, Deputy Director, OHA (June 16, 2016) (NEMA Comments).

In their comments, the Joint Commenters generally oppose Siemens' request for exception relief, stating that on the basis of the public version of the Siemens' Application for Exception, they are unable to assess whether or to what extent the electric motors utilized in Siemens' medical diagnostic equipment are subject to the Final Rule. *See* June 16, 2016, Letter from Joint Commenters to OHA, at 2. In its comments, NEMA supports Siemens' exception request, noting the possible adverse impact upon patients and their healthcare providers absent exception relief, and that Siemens has "indicated [its] plan to bring [its] products into compliance with the new DOE energy conservation standard for electric motors in a reasonable time period, taking into consideration the logistics of compliance with FDA regulation." NEMA Comments at 2.

II. Analysis

Section 504 of the Department of Energy Organization Act, 42 U.S.C. § 7194(a), authorizes the Secretary of Energy to make "such adjustments to any rule, regulation, or order" issued under the EPCA, consistent with the other purposes of the Act, as "may be necessary to prevent special hardship, inequity, or unfair distribution of burdens." The Secretary has delegated this authority to

the DOE Office of Hearings and Appeals (OHA), which administers exception relief pursuant to procedural regulations codified at 10 C.F.R. Part 1003, Subpart B. Under these provisions, persons subject to the various product efficiency standards of Part 430, promulgated under DOE's rulemaking authority, may apply to OHA for exception relief. *See, e.g., Sauder Fuel, Inc.*, OHA Case No. TEE-0059 (2009); *Diversified Refrigeration*, Inc., OHA Case No. VEE-0073 (2001); *Amana Appliances*, OHA Case No. VEE-0054 (1999).

We have carefully evaluated Siemens' Application for Exception, as well as the comments received from interested parties. In performing this evaluation, we are mindful that the DOE's adoption of the Electric Motor Efficiency Standards is fully consistent with the policy objectives of the EPCA. The revised standard will not only save money for consumers, but will also conserve significant amounts of energy for the nation as a whole.[7] In view of the nation's increasing energy needs, the benefits of energy conservation cannot be overstated. Apart from these energy savings that DOE is required to consider as part of its comprehensive analysis in assessing whether a standard is technologically feasible and economically justified, the higher efficiency standard will also have substantial environmental benefits by contributing to the overall reduction of greenhouse gas emissions and air pollution. Consequently, an exception to the revised efficiency standards is warranted only in those limited circumstances where relief is necessary to prevent a special hardship, inequity, or unfair distribution of burdens. 10 C.F.R. § 1003.20(a). We have determined that such circumstances exist in the present case and that Siemens should therefore be granted exception relief.

On the basis of the information provided by Siemens in its Application for Exception and supplemental filings, we have concluded that the firm will suffer a special hardship in the absence of exception relief. In its Final Supplement, filed on September 20, 2016, Siemens shows that sales of new MRI and CT diagnostic equipment and providing replacement motors for such equipment accounted for approximately XX% of the firm's annual revenues, on average, during fiscal years XXXX XXX XXX. *See* Final Supplement, Response to Question 2. Data provided by Siemens further shows that the firm currently has XXX pending orders for new MRI and CT equipment from various healthcare providers nationwide, that is due to be delivered during the XXX XXXX XXX XXXX XXXX XXX. *See* Final Supplement, Appendix A. Regarding replacement motors, data shows that Siemens has an insufficient quantity of replacement motors for MRI and CT equipment to meet projected demand, and the firm will therefore be required to import additional replacement motors to meet the maintenance and service obligations to its customers. *See* Final Supplement, Response to Question 1.[8]

[7] DOE estimates that the Electric Motor Efficiency Standards will save approximately 7.0 quads of energy over 30 years (2016 through 2045). A quad is a unit of energy equal to 10^{15} (a short-scale quadrillion) BTU. The annualized energy savings (0.23 quad) is equivalent to one percent of total U.S. industrial primary energy consumption in 2013. *See* 79 Fed. Reg. at 30938.

[8] More specifically, in the information submitted by Siemens, the firm projects: (1) a demand for XX CT replacement motors during the period XXXX XXX XXXX XXX XXXXX (Siemens' revised compliance date for CT motors), while the firm has only XX CT replacement motors in inventory as of XXXX XXX; and (2) a demand for XX MRI

Moreover, we believe that other factors favor the granting of exception relief in this case. In prior decisions of this Office, we determined that the same factors considered by the agency in promulgating energy conservation standards are useful in evaluating claims for exception relief. *See, e.g., Philips Lighting Co., et al.*, OHA Case Nos. EXC-12-0001, *et al.* (2012); *Maytag Corp.*, OHA Case No. TEE-0022 (2005); *Viking Range Corp.*, OHA Case No. VEE-0075 (2000). These factors are specified in section 325 of the EPCA and include the economic impact on the manufacturers and consumers, net consumer savings, energy savings, impact on product utility, impact on competition, need for energy conservation, and other relevant factors. EPCA § 325(o)(2)(B)(i), 42 U.S.C. § 6295(o)(2)(B)(i). In the present case, we find that the failure to provide exception relief will not only result in a substantial adverse impact upon Siemens but upon its customers, healthcare and their patients, as well. In the latter regard, we concur with the observations made by NEMA in its comments:

> We are persuaded by what we believe is a very significant, if not unique factor in this case: the need to timely deliver new medical devices and repair installed medical devices to avoid downtime that could impact patient care in certain cases; patients who need a timely diagnosis, and their healthcare providers, should not be negatively impacted due to this problem in medical imaging equipment that cannot be timely repaired. Another unique factor in the public interest . . . is the importance of compliance with FDA regulations relating to safety and efficacy of medical devices.

NEMA Comments at 2. Finally, we believe that granting exception relief to Siemens in this case will not impede the energy conservation goals of the EPCA. The incremental energy usage attributable to the small number of electric motors covered by the exception relief that we approve in this decision is negligible in relation to the overall energy consumption savings portended by the new Electric Motor Efficiency Standards. *See* note 6, *supra.*

We have therefore determined that Siemens should be granted exception relief with respect to the MRI and CT motors imported by the firm for new medical devices and as replacement motors. Such exception relief shall be limited to the time period that Siemens now projects for bringing its covered MRI and CT devices into compliance: 1) XXXX XXX XXX, for its covered CT devices, and 2) XXXX XXX XXX, for its covered MRI devices. *See* Siemens' September 20, 2016, Submission (Final Supplement) at 1.

It Is Therefore Ordered That:

(1) The Application for Exception filed by Siemens Medical Solutions USA Inc. and Siemens Healthcare Diagnostics Inc. (Siemens), on May 31, 2016, OHA Case No. EXC-16-0012, is hereby granted as set forth in paragraph (2) below.

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replacement motors during the period XXXX XXX XXXX XXXX XXXX (Siemens' revised compliance date for MRI motors), while the firm has only XX MRI replacement motors in inventory as of XXXX XXX.

(2) Notwithstanding the June 1, 2016, compliance date of the Energy Conservation Program: Energy Conservation Standards for Commercial and Industrial Electric Motors, published on May 29, 2014, 79 Fed. Reg. 30934 (Final Rule), and codified at 10 C.F.R. § 431.25(g) through § 431(l), Siemens is granted exception relief as follow:

> (a) the compliance date of the Final Rule is hereby established as XXXX XXX XXX, for the following XXX models of electric motors: XXXX XXXX XXXX XXXXX XXXXXX XXXXXX XXXXX XXXX XXXX XXXX; that are imported by Siemens as a component of, or for use in, new Computed Tomography medical devices sold by Siemens, or imported by Siemens and sold as replacement motors in such devices, and for which Siemens is the official importer of record; and
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> (b) the compliance date of the Final Rule is hereby established as XXX XXXX, for the following XXX models of electric motors: XXXXXX XXXXX XXXX XXXXX XXXXXX XXXXX XXXXX XXXX XXXXXX XXXXX XXXXX XXXXXX XXXXXX XXXX XXXXXX XXX XXXX XXX XXXXXX XXX XXX XXXXX XXXX XXXXX XXXXX XXXXXX XXXXX XXX XXX; that are imported by Siemens as a component, or for use in, new Magnetic Resonance Imaging medical devices sold by Siemens, or imported by Siemens and sold as replacement motors in such devices, and for which Siemens is the official importer of record.

(3) Any person aggrieved by the approval of exception relief in this Decision and Order may file an appeal with the Office of Hearings and Appeals in accordance with 10 C.F.R. Part 1003, Subpart C.

Poli A. Marmolejos
Director
Office of Hearings and Appeals

Date: November 9, 2016