

Before the
Federal Communications Commission
Washington, D.C. 20554

In the Matter of)
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GE Healthcare Petition for Waiver of the)
Commission’s Part 2 Rules for Certain)
Part 15, 18, and 95 Medical Devices)
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ORDER

Adopted: May 11, 2020

Released: May 11, 2020

By the Acting Chief, Office of Engineering and Technology; Chief, Wireless Telecommunications Bureau:

I. INTRODUCTION

1. By this Order, we grant a request by GE Healthcare (GEHC) for waiver of certain provisions of title 47 of the Code of Federal Regulations (CFR) in part 2, part 15, part 18, and part 95 to allow for the marketing, operation, and importation of medical devices that have not yet received equipment authorization under part 2, subpart J of the Commission’s rules.¹ We also waive, sua sponte, certain part 95 rules in order to effectuate the request, as described below. This action benefits the public interest by allowing GEHC to overcome disruptions in the medical device supply chain as it addresses the surge in demand caused by the COVID-19 pandemic and the declared state of national emergency.² We find that such devices, when marketed, operated, and imported under the specified waiver conditions, will benefit medical professionals in helping with patient care during the national emergency and will not have a detrimental effect on the overall integrity of our equipment authorization program.

II. BACKGROUND

2. The COVID-19 pandemic has placed an unprecedented strain on the U.S. healthcare system as it struggles to increase capacity at healthcare facilities.³ GEHC claims that the pandemic’s impact on device component suppliers, accredited test laboratories, and Telecommunications Certification Bodies (TCBs) has adversely impacted GEHC’s ability to increase production capacity and maintain a robust supply chain of patient monitoring, diagnostic ECG, diagnostic imaging, and therapeutic device supplies

¹ GE Healthcare Petition for Limited, Expedited Waiver of the Commission’s Part 2 Rules for Certain Part 15, 18, and 95 Medical Devices, (filed April 17, 2020), <https://www.fcc.gov/ecfs/filing/1041732174724> (GEHC Waiver Request). See also 47 CFR parts 2, 15, 18, and 95.

² Proclamation No. 9994, 85 Fed. Reg. 15337 (Mar. 13, 2020). The COVID-19 pandemic endangers numerous American lives with a respiratory illness that continues to spread at an alarming rate throughout the United States. See Centers for Disease Control and Prevention, Coronavirus (COVID-19), <https://www.cdc.gov/coronavirus/2019-ncov/index.html> (last visited Apr. 24, 2020); see also Johns Hopkins Coronavirus Resource Center, <https://coronavirus.jhu.edu/map.html> (last visited Apr. 24, 2020).

³ 85 Fed. Reg. at 15337.

that are essential to intensive care units (ICUs).⁴ Thus, GEHC is seeking alternative device and component suppliers, and expects to rely on such sources until the supply chain can keep up with the demand created by COVID-19.⁵ Many of GEHC's devices, including those incorporating a new component, would require a new or modified FCC equipment certification, thus delaying their ability to provide medical facilities with the equipment needed to treat the COVID-19 virus.⁶ To avoid further delays in making these vital supplies available in the U.S., GEHC requests limited waivers of the Commission's radio-frequency (RF) device equipment requirements to allow specific medical devices to be marketed, operated, and imported prior to such equipment receiving an equipment authorization grant.⁷ In particular, GEHC seeks a waiver for medical devices marketed to healthcare providers and operated on the premises of healthcare facilities at the direction of authorized health care providers throughout the U.S. and its territories. Such devices include, but are not limited to, the following:

- Bedside patient monitors; telemetry transmitters; and antenna infrastructure;
- Wearable patient monitors; wireless sensors;
- Diagnostic testing ECG analysis systems; and
- Mobile radiology; portable X-rays.⁸

GEHC notes that these devices operate using various protocols, in different services, and in several frequency bands:

- Near Field Communications: 13.56 MHz;
- RFID: 902 – 928 MHz;
- Bluetooth: 2.4 – 2.4835 GHz;
- Wi-Fi: 2.4 – 2.4835 GHz; 5.150 – 5.250 GHz; 5.250 – 5.350 GHz; 5.470 – 5.725 GHz; 5.725-5.835 GHz;
- Wireless Medical Telemetry Service: 608 – 614 MHz; 1.395 – 1.4 GHz; and
- Medical Body Area Networks: 2.36 – 2.4 GHz.⁹

III. DISCUSSION

3. Any provision of the Commission's rules may be waived upon a showing of good cause.¹⁰ Good cause may be found "where particular facts would make strict compliance inconsistent with the public interest."¹¹ "[A] general rule, deemed valid because its overall objectives are in the public interest, may not be in the 'public interest' if extended to an applicant who proposes a new service that will not undermine the policy, served by the rule, that has been adjudged in the public interest."¹²

⁴ GEHC Waiver Request at 1. Current data suggests that the quantity of device testing to date for 2020 is similar to that during the same time period for 2019. See <https://apps.fcc.gov/oetcf/eas/reports/GenericSearch.cfm>. However, there is potential for residual delays based on various state and local orders that limit or prevent certain business operations and functions, which could include both manufacturing and testing facilities.

⁵ *Id.* at 2.

⁶ *Id.*

⁷ *Id.* at 4-7.

⁸ *Id.* at 8.

⁹ *Id.*

¹⁰ 47 CFR § 1.3.

¹¹ *Northeast Cellular Tel. Co., L.P. v. FCC*, 897 F.2d 1164, 1166 (D.C. Cir. 1990) (citing *WAIT Radio v. Federal Communications Com.*, 418 F.2d 1153, 1159 (D.C. Cir. 1969)).

A. Overall public interest

4. GEHC asserts that granting its waiver request will shorten the time to market for medical devices that require a design change or new equipment authorization without introducing undue risk of harmful interference.¹³ Thus, GEHC concludes that the waiver would serve the public interest by ensuring the continued availability of its medical devices, which are likely to save lives and facilitate U.S. recovery from the global pandemic.¹⁴ GEHC states the Commission's marketing, operating, and importing restrictions are essentially intended to limit the risk of harmful interference caused by unauthorized devices.¹⁵ In this regard, GEHC has proposed numerous conditions and time limitations that it believes will ensure that the underlying purpose of the Commission's rules is not undermined.

5. As proposed by GEHC, the waivers would only apply to GEHC medical devices that operate in accordance with parts 15, 18, and 95 of the Commission's rules.¹⁶ GEHC or its authorized representative would test for compliance with technical requirements for radiated emissions,¹⁷ occupied bandwidth,¹⁸ maximum conducted output power,¹⁹ and radiation exposure limits²⁰ applicable to the covered devices.²¹ Operations would be limited to the premises of "health care facilities" at the direction of "authorized health care providers."²² For each device covered under the waiver, GEHC would submit an equipment authorization application to an FCC-authorized TCB within 180 days of initial marketing of that device.²³ GEHC requests a waiver term limited to eighteen months, indicating that it expects this to be sufficient time to acquire the necessary equipment authorizations.²⁴ Additionally, GEHC would label devices to notify customs officials, potential purchasers, and device operators that the device has not received FCC equipment authorization and is marketed, operated, and imported pursuant to a Commission waiver.²⁵ Finally, GEHC would maintain a list of all covered devices that are marketed and imported, along with the healthcare facilities to which covered devices are sent, and it would ensure that

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¹² *Wait Radio*, 418 F.2d at 1157.

¹³ GEHC Waiver Request at 4.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ More specifically, the waiver request is limited to GEHC medical devices operating under either: (1) 47 CFR § 15.225; (2) 47 CFR § 15.247; (3) 47 CFR § 15.407; (4) 47 CFR part 15, subpart B (if not already exempt) (*see* 47 CFR 15.103(e)); (5) 47 CFR part 18; (6) 47 CFR part 95, subpart H; or (7) Medical Body Area Network service rules under 47 CFR part 95, subpart I. GEHC Waiver Request at 9.

¹⁷ *See, e.g.*, 47 CFR §§ 15.109, 15.209.

¹⁸ *See, e.g.*, 47 CFR §§ 15.247(a)(1)(i), 15.407(h)(2)(iv).

¹⁹ *See, e.g.*, 47 CFR §§ 15.247(b)(3), 15.407(a)(1)(i).

²⁰ *See, e.g.*, 47 CFR § 2.1093.

²¹ GEHC anticipates that this testing would be conducted at laboratories operated by medical device manufacturers, including GEHC, which may not be accredited, but GEHC would seek to ensure that the laboratories use good engineering practices. GEHC Waiver Request at 9.

²² GEHC requests that this condition recognize that the term "health care facilities" includes temporary "field hospitals" used to expand healthcare capacity in response to COVID-19. GEHC Waiver Request at 8-9.

²³ GEHC Waiver Request at 10.

²⁴ *Id.*

²⁵ *Id.*

any device that does not receive the appropriate equipment authorization before the waiver expires would be rendered inoperable or retrieved.²⁶

6. We concur with GEHC's assertion that a waiver of the rules as requested is in the public interest because such waiver would help U.S. healthcare providers to address the current COVID-19 pandemic during this national emergency. With the conditions we place on this waiver, these actions will not undermine the policy behind the Commission's equipment authorization regulations.

B. Specific waivers

7. *Certification requirements.* The Commission's rules generally require authorization of RF devices prior to marketing and operating such devices in the United States.²⁷ Similar restrictions limit the number of devices that can be imported into the U.S. prior to equipment authorization.²⁸ The devices for which GEHC seeks a waiver require authorization via the Commission's equipment certification procedures.²⁹ A certification is approved by the Commission, or issued by a TCB and authorized under the authority of the Commission, based on representations and test data submitted by the applicant.³⁰ Data supporting a certification application must be based upon tests that are performed in a Commission-acknowledged accredited laboratory.³¹ GEHC states that, as the medical device industry struggles to increase production capacity and meet increasing demand, the many devices that will require recertification will flood TCBs and create delays.³² As GEHC is forced to rely on equipment that requires new certifications or modifications to existing certifications, it wishes to temporarily delay, but still ultimately fully complete, the certification process to enable it to provide vital equipment to healthcare facilities in an expeditious manner.³³ Thus, it seeks waivers of the certification requirements for marketing, operating, and importing RF devices, under certain conditions.³⁴

1. Marketing

8. Section 2.803(c)(2)(ii) of the Commission's rules provides limited exceptions for marketing an RF device in "the conceptual, developmental, design or pre-production stage" prior to receiving equipment authorization if: (1) the device complies with the Commission's rules, waivers of the Commission's rule that are in effect, or adopted rules that are not yet effective;³⁵ (2) marketing is limited to non-residential business, commercial, industrial, scientific, or medical users; and (3) prospective buyers are advised in writing of the device's status at the time of the offer for sale and the device complies with the Commission's rules at the time of delivery.³⁶

²⁶ *Id.* at 11.

²⁷ 47 CFR § 2.803(b). "Marketing" in this context "...includes sale or lease, or offering for sale or lease, including advertising for sale or lease, or importation, shipment, or distribution for the purpose of selling or leasing or offering for sale or lease." *See* 47 CFR 2.803(a). *See* 47 CFR § 2.805 for the rules which generally prohibit operation prior to equipment certification.

²⁸ 47 CFR §§ 2.1203 and 2.1204.

²⁹ *See* 47 CFR § 2.901(a); *see also* 47 CFR part 18.

³⁰ 47 CFR § 2.907.

³¹ 47 CFR § 2.948(a).

³² GEHC Waiver Request at 2.

³³ *Id.*

³⁴ 47 CFR §§ 2.803(c)(2)(ii), 2.1204(a)(3), 2.805(d).

³⁵ "Limited marketing is permitted . . . for devices that could be authorized under the current rules; could be authorized under waivers of such rules that are in effect at the time of marketing; or could be authorized under rules that have been adopted by the Commission but that have not yet become effective." 47 CFR 2.803(c)(2).

9. GEHC specifically requests waiver of the “conceptual, developmental, design or pre-production stage” limitation of the marketing exception.³⁷ GEHC asserts that the Commission’s marketing rules were designed to stop mass-marketed devices from reaching the public before a grant of equipment authorization had been obtained.³⁸ GEHC suggests that its proposed conditions to limit marketing of its devices to healthcare providers for a limited period of time, and to track these devices and eventually obtain equipment authorization or remove and dispose of them, would be consistent with the intent of the rule.³⁹

10. We find that the conditions GEHC suggested will enable it to maintain control of the devices until such time that it can complete the equipment authorization process for the devices and ensure compliance with the Commission’s rules. A waiver of this type would not undermine the intent of the rule and, considering the public interest benefits of the request, we find it warranted to waive the section 2.803(c)(2)(ii) requirement allowing RF devices in the “conceptual, developmental, design or pre-production stage,” to be marketed if they meet certain criteria, subject to the conditions described in this Order. Consistent with this finding, we also waive section 95.391 of the Commission’s rules, to the extent necessary, in order to permit the manufacture, import, or sale of equipment prior to certification in accordance with the conditions described in this Order.⁴⁰

2. Operation

11. Section 2.805(d) provides an exception to the Commission’s general prohibition against operating RF devices prior to equipment authorization.⁴¹ The exception allows devices to be operated prior to authorization so long as they are designed to operate solely under parts 15, 18, or 95 of the Commission’s rules and the device is operated in compliance with the Commission’s rules and for certain limited purposes.⁴² GEHC states that it would take measures to ensure that devices marketed and operated under the requested waiver comply with applicable FCC technical rules, and thus minimize the risk of harmful interference.⁴³

12. Although GEHC’s devices would be operated for purposes other than those identified in the exception at section 2.805(d)(2), we find that, under certain conditions, operating such devices only on the premises of healthcare facilities at the direction of authorized healthcare providers would not undermine the intent of the rule. Accordingly, considering the public interest benefits of the request, we find it warranted to waive the section 2.805(d)(2) operational purpose restriction, in accordance with the conditions described in this Order.

13. Consistent with our finding that it is in the public interest to grant GEHC’s request to waive section 2.805(d)(2), we also waive, *sua sponte*, the following part 95 rule sections in order to permit the operation of equipment prior to certification: section 95.335, section 95.337, and section 95.361.⁴⁴ We

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³⁶ 47 CFR § 2.803(c)(2)(ii).

³⁷ GEHC Waiver Request at 5.

³⁸ *Id.*

³⁹ *Id.* at 5-6.

⁴⁰ See 47 CFR § 95.391. GEHC requests a waiver of this rule section to the extent necessary. GEHC Waiver Request at 5, n.15.

⁴¹ See 47 CFR § 2.805.

⁴² The purposes include demonstration at a trade show or exhibition or evaluation of “performance and determination of customer acceptability” during the developmental, design, or pre-production states, with certain restrictions. 47 CFR § 2.805(d)(2).

⁴³ GEHC Waiver Request at 6.

waive these rule sections to the extent necessary to permit GEHC's devices to operate as described in its request and in accordance with the conditions described in this Order.

3. Importation

14. Section 2.1204(a)(3) allows for the importation of 4,000 or fewer units of an unauthorized RF device for the purposes of testing and evaluation, provided the devices are not offered for sale or marketed.⁴⁵ The Commission's intent when adopting these rules was to keep RF devices which are not capable of complying with our technical requirements from being distributed to the general public and thereby reducing the potential harmful interference capable of being caused to authorized communications.⁴⁶ GEHC asserts that they would take measures to ensure that medical devices marketed and operated under this waiver would comply with applicable FCC technical rules and therefore present minimal risk of harmful interference.⁴⁷

15. Although GEHC's intended use for the relevant devices is not "testing and evaluation," we believe that by limiting operation to healthcare facilities and performing limited compliance testing, in addition to the other conditions we are placing on the devices, the requested waiver would not undermine the intent of the rule. Accordingly, considering the public interest benefits of the request, we find it warranted to waive the section 2.1204(a)(3) restriction on the number of unauthorized devices that may be imported by a single party, in accordance with the conditions described in this Order.

IV. CONCLUSION

16. Based on our finding that marketing, operating, and importing the listed GEHC medical devices prior to full compliance with our equipment authorization requirements would not undermine the intent of the relevant Commission rules and, because of the predominant public interest in GEHC expeditiously deploying devices to assist with the current COVID-19 public health emergency, we GRANT THE WAIVER REQUEST AND WAIVE THE FOLLOWING RULES: 47 CFR §§ 2.803(c)(2)(ii), 2.805(d), 2.1204(a)(3), and 95.391. We waive, sua sponte, the following rules: 47 CFR §§ 95.335, 95.337, and 95.361.

17. This waiver will apply to both current FCC authorized devices that experience a design change⁴⁸ and new products that have not previously received an FCC equipment authorization.⁴⁹ GEHC medical devices covered by this waiver may be marketed, operated, or imported subject to the following conditions:

- The waiver is limited to GEHC medical devices operating under either: (1) 47 CFR § 15.225; (2) 47 CFR § 15.247; (3) 47 CFR § 15.407; (4) 47 CFR part 15, subpart B (if not already

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⁴⁴ 47 CFR §§ 95.335 (requires transmitters to be granted equipment certification prior to use), 95.337 (prohibits operation of modified equipment where the modification has not been approved), and 95.361 (requires transmitters to be certified).

⁴⁵ 47 CFR § 2.1204(a)(3)(i).

⁴⁶ *Amendment of Part 2 with Respect to Importation of Certain Electronic Equipment*, Report and Order, 37 Rad. Reg.2d 847, para. 10 (1975).

⁴⁷ GEHC Waiver Request at 6-7.

⁴⁸ See 47 CFR § 2.1043.

⁴⁹ See 47 CFR §§ 15.101, 15.201.

- exempt); (5) 47 CFR part 18; (6) 47 CFR part 95, subpart H; and (7) medical body area network service rules under 47 CFR part 95, subpart I;⁵⁰
- Prior to marketing, GEHC or its authorized representative must test the covered devices for compliance with all applicable technical and operational rules, including radiated emissions,⁵¹ occupied bandwidth,⁵² maximum conducted output power,⁵³ duty cycle, sharing/operational requirements, and radiation exposure limits,⁵⁴ ensuring that any non-accredited laboratories conducting such testing use good engineering practices;
 - Operation of covered GEHC medical devices under this waiver is limited to the premises of “healthcare facilities” at the direction of “authorized health care providers,” the term “healthcare facilities” includes temporary “field hospitals” used to expand healthcare capacity in response to COVID-19;⁵⁵
 - Within 180 days after initial marketing of a device, based upon the date the device was first distributed to a healthcare facility, GEHC must submit an equipment authorization application for each device covered under this waiver, in accordance with the procedures of part 2, subpart J of the Commission’s rules;
 - Each GEHC medical device covered by this waiver must be labeled as follows:

“The marketing, importation, and operation of this device are permitted under a Federal Communications Commission rule waiver. This device can be operated only on the premises of healthcare facilities and must not cause harmful interference.”

- GEHC devices covered under this waiver also must comply with any otherwise applicable FCC labeling requirements. Once GEHC devices covered by this waiver receive appropriate equipment authorization, GEHC must ensure that such devices are relabeled with the relevant FCC ID and any other applicable labeling.
- This waiver expires eighteen months from the effective date of this Order. Any request to extend the term of this waiver must include: a detailed showing of new or continuing conditions that warrant relief, a demonstration of GEHC’s efforts to meet the needs of the industry within the constraints of FCC rules, and be filed sufficiently in advance of the expiration of the relief to permit agency consideration.
- GEHC must maintain a list of all covered devices that are imported and marketed, and of the healthcare facilities to which covered devices were distributed. Within thirty (30) days after expiration of the waiver, GEHC must notify the Office of Engineering and Technology that all devices that were marketed, imported, and operated under this waiver and for which authorization has not been obtained have been rendered inoperable or retrieved by GEHC before the expiration of this waiver.

⁵⁰ Such part 95 devices must still meet FCC coordination requirements to ensure that harmful interference is not caused to existing entities operating in the same frequency band or adjacent bands, and this grant of waiver does not include transmissions from any implanted devices. *See* 47 CFR §§ 95.2309, 95.2509.

⁵¹ *See, e.g.*, 47 CFR §§ 15.109, 15.209.

⁵² *See, e.g.*, 47 CFR §§ 15.247(a)(1)(i), 15.407(h)(2)(iv).

⁵³ *See, e.g.*, 47 CFR §§ 15.247(b)(3), 15.407(a)(1)(i).

⁵⁴ *See, e.g.*, 47 CFR § 2.1093.

⁵⁵ We note that part 95 includes specific definitions of healthcare facilities related to the eligibility to operate of wireless medical telemetry service and Medical body area network devices. 47 CFR §§ 95.2303, 95.2507.

18. Accordingly, pursuant to authority in Sections 0.31, 0.241, and 1.3 of the Commission's rules, 47 C.F.R. §§ 0.21, 0.241, and 1.3, and sections 4(i), 302, 303(e), and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. §§ 154(i), 302, 303(e), and 303(r), IT IS ORDERED that the Request for Waiver filed by GE Healthcare, IS GRANTED, consistent with the terms of this Order. This action is effective upon release of this Order.

FEDERAL COMMUNICATIONS COMMISSION

Ronald T. Repasi
Acting Chief, Office of Engineering and Technology

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Chief, Wireless Telecommunications Bureau