3060-0936
August 2016

SUPPORTING STATEMENT

Sections 95.1215, 95.1217, 95.1223 and 95.1225
Medical Device Radiocommunication Service (MedRadio)

A. Justification:

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirement that necessitates the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

The Federal Communications Commission is requesting that the Office of Management and Budget (OMB) approve for a period of three years an extension for the information collection requirements contained in this collection.

The information collection requirements[1] that are approved under this information collection are contained in 47 CFR Sections 95.1225(b) and (c), 95.1217(a)(3) and (c), 95.1223 and 95.1225 which relate to the Medical Device Radiocommunication Service (MedRadio).

Statutory authority for this collection of information is contained in 47 U.S.C. 154, 303 unless otherwise noted.

This information collection does not affect individuals or households; thus, there are no impacts under the Privacy Act.

2. Indicate how, by whom and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

The information collection requires that MedRadio transmitters include with each transmitting device the following statement: "This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150-406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved

[1] Question 2 of the supporting statement gives detailed information on the various information collections which are approved under this collection.

by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference."

The information collection also requires manufacturers of MedRadio programmer/control transmitters to include the following statement on the device in a conspicuous location, or if it is not feasible to place the statement on the device, in the instruction manual:

> "This device may not interfere with stations operating in the 400.150-406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation."

Section 95.1215(b), Labeling requirement.

(b) Manufacturers of MedRadio transmitters operating in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands must include with each transmitting device the following statement:

> **"**This transmitter is authorized by rule under the MedRadio Service (47 CFR part 95). This transmitter must not cause harmful interference to stations authorized to operate on a primary basis in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands, and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the MedRadio Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference."

MedRadio programmer/control transmitters operating in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands shall be labeled as provided in part 2 of this chapter and shall bear the following statement in a conspicuous location on the device:

"This device may not interfere with stations authorized to operate on a primary basis in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands, and must accept any interference received, including interference that may cause undesired operation."

Section 95.1215 (c), Disclosure policies.

(c) Manufacturers of MedRadio transmitters operating in the 2360-2400 MHz band must include with each transmitting device the following statement:

> "This transmitter is authorized by rule under the MedRadio Service (47 CFR Part 95). This transmitter must not cause harmful interference to stations authorized to operate on a primary basis in the 2360-2400 MHz band, and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the MedRadio Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference."

Section 95.1225(c), Frequency Coordinator Requirements.

(c) The frequency coordinator shall:

(1) Provide registration and coordination of MBAN operations to all eligible health care facilities on a non-discriminatory basis;

(2) Provide MBAN registration and coordination services on a not-for-profit basis;

(3) Notify the Commission of its intent to no longer serve as frequency coordinator six months prior to ceasing to perform these functions; and

(4) Transfer the MBAN registration data in usable form to a frequency coordinator designated by the Commission if it ceases to be the frequency coordinator.

The information collection contained in sections 95.1215 and 95.1217 require manufacturers of transmitters for the MedRadio to include with each transmitting device a statement regarding harmful interference and to label the device in a conspicuous location on the device. The requirements will allow use of potential life-saving medical technology without causing interference to other users of the 400.150-406.000 MHz band. Sections 95.1223 and 95.1225 requires that the Commission designate a frequency coordinator to manage the operation of "medical body area networks" (MBAN) in the 2360 MHz-2390 MHz band to

ensure that the MBAN devices can successfully operate on a secondary basis in the 2.3 GHz band without the need for individual licenses.

Section 95.1217(a)(3) and (c), Labeling requirements.

(a) (3) MedRadio programmer/control transmitters operating in the 2360-2400 MHz band shall be labeled as provided in part 2 of this chapter and shall bear the following statement in a conspicuous location on the device:

> "This device may not interfere with stations authorized to operate on a primary basis in the 2360-2400 MHz band, and must accept any interference received, including interference that may cause undesired operation."

The statement may be placed in the instruction manual for the transmitter where it is not feasible to place the statement on the device.

(c) MedRadio transmitters shall be identified with a serial number, except that in the 2360-2400 MHz band only the MedRadio programmer/controller transmitter shall be identified with a serial number. The FCC ID number associated with a medical implant transmitter and the information required by §2.925 of this chapter may be placed in the instruction manual for the transmitter and on the shipping container for the transmitter, in lieu of being placed directly on the transmitter.

The designated frequency coordination will have the responsibility to maintain an accurate engineering database for registration and frequency coordination in the 2360-2390 MHz band.

Section 95.1223, Registration and frequency coordination in the 2360-2390 MHz Band.

(a) A health care facility must register all MBAN devices it proposes to operate in the 2360-2390 MHz band with a frequency coordinator designated under § 95.1225. Operation of these devices in the 2360-2390 MHz band is prohibited prior to the MBAN coordinator notifying the health care facility that registration and coordination (to the extent coordination is required under paragraph (c) of this section), is complete. The registration must include the following information:

(1) Specific frequencies or frequency range(s) within the 2360-2390 MHz band to be used, and the capabilities of the MBAN equipment to use the 2390-2400 MHz band;

(2) Effective isotropic radiated power;

(3) Number of control transmitters in use at the health care facility as of the date of registration including manufacturer name(s) and model numbers and FCC identification number;

(4) Legal name of the health care facility;

(5) Location of control transmitters (e.g., geographic coordinates, street address, building);

(6) Point of contact for the health care facility (e.g., name, title, office, phone number, fax number, e-mail address); and

(7) In the event an MBAN has to cease operating in all or a portion of the 2360-2390 MHz band due to interference under § 95.1211 or changes in coordination under paragraph (c) of this section, a point of contact (including contractors) for the health care facility that is responsible for ensuring that this change is effected whenever it is required (*e.g.*, name, title, office, phone number, fax number, e-mail address). The health care facility also must state whether, in such cases, its MBAN operation is capable of defaulting to the 2390-2400 MHz band and that it is responsible for ceasing MBAN operations in the 2360-2390 MHz band or defaulting traffic to other hospital systems.

(b*)* Notification: A health care facility shall notify the frequency coordinator whenever an MBAN control transmitter in the 2360-2390 MHz band is permanently taken out of service, unless it is replaced with transmitter(s) using the same technical characteristics as those reported on the health care facility's registration. A health care facility shall keep the information contained in each registration current, shall notify the frequency coordinator of any material change to the MBAN's location or operating parameters, and is prohibited from operating the MBAN in the 2360-2390 MHz band under changed operating parameters until the frequency coordinator determines whether such changes require coordination with the AMT coordinator designated under § 87.305 of this chapter and, if so, the coordination required under paragraph (c) of this section has been completed.

(c) Coordination procedures. The frequency coordinator will determine if an MBAN is within the line of sight of an AMT receive facility in the 2360-2390 MHz band and notify the health care facility when it may begin MBAN operations under the applicable procedures in (c)(1) or (2) of this section.

(1) If the MBAN is beyond the line of sight of an AMT receive facility, it may operate without prior coordination with the AMT coordinator, provided that the MBAN coordinator provides the AMT coordinator with the MBAN registration information and the AMT coordinator concurs that the MBAN is beyond the line of sight prior to the MBAN beginning operations in the band.

(2) If the MBAN is within line of sight of an AMT receive facility, the MBAN frequency coordinator shall achieve a mutually satisfactory coordination agreement with

the AMT frequency coordinator prior to the MBAN beginning operations in the band. Such coordination agreement shall provide protection to AMT receive stations consistent with "International Telecommunication Union (ITU) Recommendation ITU-R M.1459, "Protection criteria for telemetry systems in the aeronautical mobile service and mitigation techniques to facilitate sharing with geostationary broadcasting-satellite and mobile-satellite services in the frequency bands 1 452-1 525 and 2 310-2 360 MHz," May 2000," as adjusted using generally accepted engineering practices and standards that are mutually agreeable to both coordinators to take into account the local conditions and operating characteristics of the applicable AMT and MBAN facilities, and shall specify when the device shall limit its transmissions to segments of the 2360-2390 MHz band or shall cease operation in the band. This ITU document is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 and approved by the Director of Federal Register. Copies of the recommendation may be obtained from ITU, Place des Nations, 1211 Geneva 20, Switzerland, or online at http://www.itu.int/en/publications/Pages/default.aspx>. You may inspect a copy at the Federal Communications Commission, 445 12th Street, SW, Washington, DC 20554, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. "Generally accepted engineering practices and standards" include, but are not limited to, engineering analyses and measurement data as well as limiting MBAN operations in the band by time or frequency.

(3) If an AMT operator plans to operate a receive site not previously analyzed by the MBAN coordinator to determine line of sight to an MBAN facility, the AMT operator shall consider using locations that are beyond the line of sight of a registered health care facility. If the AMT operator determines that non-line of sight locations are not practical for its purposes, the AMT coordinator shall notify the MBAN coordinator upon no less than 7 days' notice that the registered health care facility must cease MBAN operations in the 2360-2390 MHz band unless the parties can achieve a mutually satisfactory coordination agreement under paragraph (c)(2) of this section.

Section 95.1225, Frequency coordinator.

(a) The Commission will designate a frequency coordinator(s) to manage the operation of medical body area networks by eligible health care facilities.

(b) The frequency coordinator shall perform the following functions:

(1) Register health care facilities that operate MBAN transmitters, maintain a database of these MBAN transmitter locations and operational parameters, and provide the Commission with information contained in the database upon request;

(2) Determine if an MBAN is within line of sight of an AMT receive facility in the 2360-2390 MHz band and coordinate MBAN operations with the designated AMT coordinator as specified in § 87.305 of this chapter;

(3) Notify a registered health care facility when an MBAN has to change frequency within the 2360-2390 MHz band or to cease operating in the band consistent with a coordination agreement between the MBAN and the AMT coordinators;

(4) Develop procedures to ensure that registered health care facilities operate an MBAN consistent with the coordination requirements under § 95.1223; and

(5) Identify the MBAN that is the source of interference in response to a complaint from the AMT coordinator and notify the health care facility of alternative frequencies available for MBAN use or to cease operation consistent with the rules.

(c) The frequency coordinator shall:

(1) Provide registration and coordination of MBAN operations to all eligible health care facilities on a non-discriminatory basis;

(2) Provide MBAN registration and coordination services on a not-for-profit basis;

(3) Notify the Commission of its intent to no longer serve as frequency coordinator six months prior to ceasing to perform these functions; and

(4) Transfer the MBAN registration data in usable form to a frequency coordinator designated by the Commission if it ceases to be the frequency coordinator.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

Prior to finalizing rule makings the Wireless Telecommunications Bureau conducts an analysis to insure that improved information technology cannot be used to reduce the burden on the public. This analysis considers the possibility of obtaining and/or computer-generating the required data from existing data basis in the Commission or other federal agencies.

Frequency registration and coordination will be provided through third party requirements by the frequency coordinator; the FCC has no requirements/restrictions on how third party coordination/notification is conducted.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in item 2 above.

This agency does not impose a similar information collection on the respondents. There are no similar data available. As a third party requirement some duplication of effort is involved for applicants; however, reasonable efforts are necessary to satisfy interference concerns.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

In conformance with the Paperwork Reduction Act of 1995, the Commission is making an effort to minimize the burden on all respondents, regardless of size. The Commission has limited the requirements to that absolutely necessary for evaluating and processing each application and to deter against possible abuses of the processes.

In addition, the devices in question are highly specialized medical devices that are manufactured only by the larger manufacturers; and therefore there is no impact on small businesses.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

The information is necessary to allow the coordinator and parties using the database to contact others users to verify information and resolve potential conflicts. Each user is responsible for determining in advance whether new devices are likely to cause or be susceptible to interference from devices already registered in the coordination database.

7. Explain any special circumstances that cause an information collection to be conducted in a manner: requiring respondents to report information to the agency more often than quarterly; requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it; requiring respondents to submit more than an original and two copies of any document; requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.
Current data collection is consistent with 5 CFR 1320.5. There are no special circumstances required for this collection of information.

8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information prior to submission to OMB.

-Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

The views of industry and the general public were solicited when the Commission published a 60-day public comment period which appeared in the *Federal Register* on June 17, 2016 (81 FR 39639). The Commission received no comments in response to the Notice in the *Federal Register*.

9. Explain any decision to provide any payment or gift to respondents, other than reenumeration of contractors or grantees.

No gifts or payment will be given to respondents for this collection.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation or agency policy.

No information is requested that would require assurance of confidentiality.

11. Provide additional justification for any questions of a sensitive nature.

There are no requests of a sensitive nature considered or those considered a private matter being sought from the applicants on this collection.

12. Provide estimates of the hour burden of the collection of information. The statement should: indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance.

Approximately 120 manufacturers (respondents), in each frequency band indicated above, will be required to include a statement and label radio devices. Informal consultation and past experience was used to arrive at the estimate of 1 hour per year per manufacturer for a total yearly burden of 120 hours.

20 (400.150-406.000 MHz band manufacturers) x 1 hour = 20 hours
20 (413-419 MHz band manufacturers) x 1 hour = 20 hours
20 (426-432 MHz band manufacturers) x 1 hour = 20 hours
20 (438-444 MHz band manufacturers) x 1 hour = 20 hours
20 (451-457 MHz band manufacturers) x 1 hour = 20 hours
20 (2360-2390 MHz band manufacturers x 1 hour) = 20 hours

Annual Burden hours: 120 hours.

It is also expected that 3,000 operators (respondents) will register with the frequency coordinator**.** The length of time to prepare the response and register the frequencies will take approximately 3 hours.

Annual Burden hours: 3,000 respondents x 3 hours/response (avg.) = **9,000 hours.**

Total Annual Burden Hours: 120 + 9,000 hours = 9,120 hours.

Total Number of Respondents: 120 manufacturers + 3,000 operators = 3,120.

Total Number of Annual Responses: 120 + 3,000 = 3,120.

In-house Cost: The Commission estimates that the hourly rate for in-house staff to be paid to fulfill the requirements is $50/hour. Therefore, the in-house costs are as follows:

3,120 hours x $50/hour = $156,000.

13. Provide estimate for the total annual cost burden to respondents or recordkeepers resulting from the collection of information. (Do not include the cost of any hour burden shown in items 12 and 14).

There are no external/consulting costs associated with this collection.

14. Provide estimates of annualized costs to the Federal government. Also provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), any other expenses that would not have been incurred without this collection of information.

Estimate of cost to Federal Government: None.

15. Explain the reasons for any program changes or adjustments.

There are no program changes for this collection. There are adjustments/decreases of $462,600 to the annual cost which are due to the Commission reevaluating the annual cost for this collection.

16. For collections of information whose results will be published, outline plans for tabulation and publication.

The collection of information is intended to ensure compliance with applicable Commission rules. The data will not be published for statistical use.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

We do not seek approval to not display the expiration date for OMB approval of the information collection.

18. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

There were no exceptions to the certification statement.

B. <u>Collections of Information Employing Statistical Methods</u>:

The information collection does not employ statistical methods.