

SUPPORTING STATEMENT

Sections 95.2593, 95.2595 and 95.2509
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 requirements¹ that are approved under this information collection are contained in 47 CFR Sections 95.2593 (MedRadio labeling requirements), 95.2595 (MedRadio disclosures) and 95.2509 (MBAN registration and frequency coordination) which relate to the Medical Device Radiocommunication Service (MedRadio).²

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 contained in sections 95.2593 and 95.2595 require manufacturers of transmitters for the MedRadio to include with each transmitting device a statement regarding harmful interference to other services they share spectrum with and to label the device with this information in a conspicuous location on the device. The requirements will allow use of potential life-saving medical technology without causing interference to other users. Section 95.2509 requires that the Commission designate a frequency coordinator to manage the operation of “medical body area networks”

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

² These rule sections were previously numbered 47 CFR Sections 95.1215, 95.1217, 95.1223 and 95.1225.

(MBAN) in the 2360 MHz-2390 MHz band to ensure that the MBAN devices can successfully operate on a secondary basis in the band without the need for individual licenses. The section also outlines the obligations of the coordinator and the MBAN device operators in the coordination process.

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 May 28, 2025 (90 FR 22482). 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 remuneration 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.

To date, 23 manufacturers have sought authorization for 149 devices across these bands. We estimate consistent growth based on past data averaged over a 10 year period will result in 15 applications that 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 15 hours.

Annual Burden hours: 15 applications x 1 hour/application = 15 hours.

There are currently 6,120 hospitals in the United States, not all will use this equipment, but we estimate 10% could wish to deploy these systems annually for a total of 612 operators (respondents) will register with the frequency coordinator annually. The length of time to prepare the response and register the frequencies will take approximately 3 hours.

Annual Burden hours: 612 respondents x 3 hours/response (avg.) = 1,836 hours.

Total Annual Burden Hours: 15 + 1,836 hours = 1,851 hours.

Total Number of Respondents: 15 manufacturers + 612 operators = 627.

Total Number of Annual Responses: 15 + 612 = 627.

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:

1,851 hours x \$50/hour = \$92,550.

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 to this information collection. There are adjustments to the collection which are due to a decrease in the estimated number of respondents. This decrease in the number of respondents is due to new data based upon equipment authorizations over the past 10 years. Therefore, the number of respondents decreased by -2,493, the number of responses decreased by -2,493 and the annual burden hours decreased by -7,269.

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. Collections of Information Employing Statistical Methods:

The information collection does not employ statistical methods.