**3060-0936**
May 2012

**SUPPORTING STATEMENT**

Revised title: § 95.1215 – Medical Device Radiocommunication Service (MedRadio) – Disclosure Policies;
§ 95.1217 – Labeling Requirements

**A. Justification:**

1. The information collection contained in sections 95.1215 and 95.1217 require manufacturers of transmitters for the Medical Device Radiocommunication Service (MedRadio)[1] 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.

   In order to obtain the full three-year clearance from OMB, the Commission is now seeking OMB approval for a revision of this currently approved information collection. There is a change in burden, see item 15 of this supporting statement.

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

   As noted on the Form 83-I, this information collection does not affect individuals or households; thus, there are no impacts under the Privacy Act.

2. The information collection requires that MedRadio transmitters must 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 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 Commission now seeks OMB approval for a revision. The Commission adopted and released a Report and Order, FCC 11-176 Amendment of Parts 2 and 95 of the Commission's Rules to Provide Additional Spectrum for the Medical Device Radiocommunication Service which 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:

[1] On November 30, 2011, the Federal Communications Commission adopted a *Report and Order* in ET Docket No. 09-36; RM 11404; FCC 11-176, which changed the term Medical Implant Communications Service (MICS) to Medical Device Radiocommunication Service (MedRadio). *See* 77 FR 4252 at *4262.

"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."

**Revised Section 95.1215(b):**

**(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."

3. 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.

4. This agency does not impose a similar information collection on the respondents. There are no similar data available.

5. 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.

6. This information is considered essential to the implementation of the Act as described above.

7. Current data collection is consistent with 5 CFR 1320.6.

8. The Commission initiated a 60-day public comment period which appeared in the Federal Register on February 29, 2012 (77 FR 12302). No PRA comments were received as a result of the notice.

9. Respondents will not receive any payments.

10. There is no need for confidentiality.

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

12. Approximately 20 manufacturers, 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 100 hours.

    (a) 20 (400.150-406.000 MHz band manufacturers) x 1 hour = 20 hours

    (b) 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

    **TOTAL ANNUAL HOUR BURDEN IS: 100 Hours.**

    **Estimate of in-house costs to respondents**: Informal consultation was used to arrive at an estimate of $6,500.00 for the 100 manufacturers to include a statement and label radio devices.

    5,000 devices x .50 per statement to produce and include = $2,500.00
    5,000 devices x 1.30 per label to produce and attach = $6,500.00

13. Estimate of cost to respondents: None.

    a. There are no capital or start-up costs.
    b. There are no operational or maintenance costs.

14. Estimate of cost to Federal Government: None.

15. With the adoption of requirements in FCC 11-176 and an increase in the number of manufacturers, the Commission is reporting an adjustment increase of +80 hours to the total annual burden.

16. The data will not be published to statistical use.

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

18. There were no exceptions to Item 19.

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

No statistical methods are employed.