Federal Communications Commission

Explanation of Non-Substantive Changes to OMB Control Number: 3060-0936:

Labeling and Recordkeeping Requirements for MedRadio Equipment

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Purpose of this Submission: This is a submission for a non-substantive change request submission to an existing information collection pursuant to 44 U.S.C. § 3507. This submission seeks to submit a non-substantive change request for the labeling and recordkeeping requirements for MedRadio Equipment approved under OMB Control Number 3060-0936. This submission is being made because the pertinent Title 47, Part 95 rules have been recodified under new section numbers without substantive changes. This recodification was in connection with a streamlining and renumbering of Part 95.

- The requirements that had been codified in Section 95.1215, Disclosure policies, paragraphs (b) and (c) are now codified in **Section 95.2595**, MedRadio disclosures, paragraphs (b) and (c), which state:

(b) For MedRadio transmitters operating in the 413-419 MHz, 426-432 MHz, 438-444 MHz and 451-457 MHz bands, the following statement applies:

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.

(c) For MedRadio transmitters operating in the 2360-2400 MHz band, the following statement applies:

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.

- The requirements that had been codified in Section 95.1217, Labeling requirement, are now codified in Section 95.2593, MedRadio labeling requirement, which states:

§ 95.2593 MedRadio labeling requirements**.**

MedRadio transmitters must be labeled in accordance with the requirements in this section.

(a) MedRadio programmer/control transmitters operating in the 401-406 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 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.

(b) 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.

(c) 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.

(d) If it is not feasible to place the statement specified by paragraph (a), (b), or (c) of this section on the device, it may be placed in the instruction manual for the transmitter instead.

(e) If a MedRadio programmer/control transmitter is constructed in two or more sections connected by wire and marketed together, the statement specified in this section is required to be affixed only to the main control unit.

(f) MedRadio transmitters shall be identified with a serial number on each device, except as noted in paragraphs (f)(1) and (2) of this section.

(1) For MedRadio transmitters that operate in the 2360-2400 MHz band, only the programmer/control transmitter shall be identified with a serial number.

(2) 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 requirements that had been codified in Section 95.1225, Frequency coordinator requirements, are now codified in Section 95.2509, MBAN registration and frequency coordination, which states:

§ 95.2509 MBAN registration and frequency coordination.

Operation of Medical Body Area Network (MBAN) devices is subject to the frequency coordination procedures in this section.

(a) The FCC 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 FCC with information contained in the database upon request;

(2) Determine if an MBAN is within line-of-sight of an Aeronautical Mobile Telemetry (AMT) receive facility in the 2360-2390 MHz band and coordinate MBAN operations with the designated AMT frequency 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 AMT frequency coordinators;

(4) Develop procedures to ensure that registered health care facilities operate an MBAN consistent with the coordination requirements under this section; 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) *Registration.* Prior to operating MBAN devices that are capable of operation in the 2360-2390 MHz band, a health care facility must register with a frequency coordinator designated under § 95.2509. Operation of MBAN 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 (e) 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) Equivalent isotropically radiated power;

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

(4) Legal name of the health care facility;

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

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

(7) In the event that an MBAN has to cease operating in all or a portion of the 2360-2390 MHz band due to interference under § 95.2525 or changes in coordination under paragraph (e) 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 address, phone number, fax number, email 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.

(d) *Notification.* A health care facility shall notify the MBAN frequency coordinator whenever an MBAN programmer/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, which will cover the replacement transmitter(s). A health care facility shall keep the information contained in each registration current and shall notify the MBAN frequency coordinator of any material change to the MBAN's location or operating parameters. In the event that the health care facility proposes to change the MBAN's location or operating parameters, the MBAN coordinator must first evaluate the proposed changes and comply with paragraph (e) of this section as appropriate before the health care facility may operate the MBAN in the 2360-2390 MHz band under changed operating parameters.

(e) *Coordination procedures.* The MBAN 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 below.

(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 frequency 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 must cease operation in the band. This ITU document is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Federal Communications Commission must publish a document in the Federal Register and the material must be available to the public. 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 (e)(2) of this section.

(f) *Coordinator functions.* The MBAN 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 FCC of its intent to no longer serve as frequency coordinator at least 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 FCC if it ceases to be the coordinator.

There are no changes to the burden hours or annual cost for this collection as a result of the non-submission change request submission.