1-yl]morpholine, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only dimethomorph in or on the commodity.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et se.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et se.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et se.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et se.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 10, 2015.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.493:

■ a. Revise the introductory text of paragraph (a).

■ b. Remove the entries in the table in paragraph (a) for ''Lettuce, head'', and ''Lettuce leaf''.

■ c. Add alphabetically the entry for ''Strawberry'' to the table in paragraph (a).

■ d. Revise the introductory text of paragraphs (c) and (d).

The additions and revisions read as follows:

§ 180.493 Dimethomorph; tolerances for residues.

(a) * * *

Tolerances are established for residues of the fungicide dimethomorph, 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propen-1-yl]morpholine, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only dimethomorph in or on the commodities.

Commodity	Parts per million
* * * * *	
Strawberry	0.90
* * * * *	

* * * * *

(c) *Tolerances with regional registrations.* Tolerances with regional registrations are established for residues of the fungicide dimethomorph, 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propen-1-yl]morpholine, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only dimethomorph in or on the commodity.

* * * * *

(d) *Indirect or inadvertent residues.* Tolerances are established for the indirect or inadvertent residues of the fungicide dimethomorph, 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propen-1-yl]morpholine, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only dimethomorph in or on the commodity.

* * * * *

[FR Doc. 2015–21192 Filed 8–28–15; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2 and 5

[ET Docket Nos. 10–236, 06–155; FCC 15–76]

Radio Experimentation and Market Trials

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document responds to three petitions for reconsideration seeking to modify certain rules adopted

in the *Report and Order* in this proceeding. In response, the Commission modifies its rules, consistent with past practice, to permit conventional Experimental Radio Service (ERS) licensees and compliance testing licensees to use bands exclusively allocated to the passive services in some circumstances; clarifies that some cost recovery is permitted for the testing and operation of experimental medical devices that take place under its market trial rules; and adds a definition of ''emergency notification providers'' to its rules to clarify that all participants in the Emergency Alert System (EAS) are such providers. However, the Commission declines to expand the eligibility for medical testing licenses.

DATES: Effective September 30, 2015.

FOR FURTHER INFORMATION CONTACT: Rodney Small, Office of Engineering and Technology, (202) 418–2452, email: *Rodney.Small@fcc.gov,* TTY (202) 418–2989.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Memorandum Opinion & Order* (*MO&O*), ET Docket Nos. 10–236 and 06–155, FCC 15–76, adopted July 6, 2015, and released July 8, 2015. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY–A257), 445 12th Street SW., Washington, DC 20554. The full text may also be downloaded at: *www.fcc.gov.* People with Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

Summary of Memorandum Opinion and Order

1. In the *Report and Order (R&O*) in this proceeding, 78 FR 25138, April 29, 2013, the Commission updated its part 5 ERS rules to add options that provide additional flexibility to keep pace with the speed of modern technological change, and an environment where creativity can thrive. Specifically, the Commission added three new types of ERS licenses to supplement the existing conventional ERS license: the program license, the medical testing license, and the compliance testing license. The Commission also modified its market trial rules to eliminate confusion and more clearly articulate its policies with respect to marketing products prior to equipment certification, including establishing a subpart for product development and market trials.

2. In this *MO&O,* the Commission responds to petitions for reconsideration of the *R&O* filed by Marcus Spectrum Solutions LLC (Marcus); Medtronic, Inc. (Medtronic); and Sirius XM Radio Inc. (Sirius XM) and EchoStar Technologies, Inc. (EchoStar).

Marcus Petition

3. In its petition, Marcus asks that the Commission reconsider a modified provision in § 5.85(a) of the Commission's rules that prohibits all experimental licensees from using bands exclusively allocated to the passive services. Marcus notes that, while the modified rule was proposed in the *Notice of Proposed Rulemaking (NPRM)* in this proceeding (76 FR 6928, February 8, 2011) and adopted in the rules appendix of the *R&O,* it is inconsistent with both the text of the *R&O* and existing policy under which conventional experimental licensees have been allowed to operate in bands allocated to the passive services. Marcus argues that there are legitimate reasons for short-term conventional experiments in some of the bands allocated for passive use. Specifically, Marcus argues that testing new concepts in modulation, high bandwidth, or other technical details in a given non-passive band that might be appropriate as a future home for a new service can be very expensive if that testing requires custom-made equipment. Marcus maintains that there is a valid reason to verify the new technical concepts in a band in which equipment is much less expensive, even though long-term use of that band might not be possible. Therefore, Marcus recommends new language for § 5.85(a) that would prohibit experimental use of the passive bands by the new types of ERS licensees and in product development and market trials, while also specifying that any conventional experimental licensee proposing use of the passive bands for an experiment must include a justification of why non-passive bands are inadequate for that experiment. The Boeing Company (Boeing) and Battelle Memorial Institute (Battelle) support grant of the Marcus Petition, and no commenting parties objects.

4. As Marcus observes, § 5.85(a) of the rules is inconsistent with both the Commission's existing treatment of conventional ERS licenses and the text of the *R&O.* This inconsistency arose in the *NPRM,* where the text proposed that only program licenses would be prohibited from using ''restricted'' bands (including passive service bands) listed in § 15.205(a) of the Commission's rules. In contrast, § 5.85(a) of the rules proposed that all experimental use of ''any frequency or frequency band exclusively allocated to the passive services'' be prohibited. This inconsistency was not addressed by any commenting party, but the Commission's stated intent in the text of the *R&O* was to continue previous practice regarding conventional ERS licenses. In addition, the Commission observes that the *R&O* stated: ''Due to the nature of the compliance testing process, the Commission will not impose on them most of the limitations and reporting requirements that it will impose on program licenses. Specifically, because compliance testing often involves emission measurements in restricted bands, compliance testing licensees will be exempt from the prohibition on operating in the restricted bands listed in § 15.205(a) of the rules and from operating in the bands allocated exclusively to the passive services.'' Thus, the Commission modifies § 5.85(a) to permit conventional and compliance testing licensees to operate on passive bands.

5. In making these modifications to § 5.85(a), the Commission observes that a number of conventional experiments have operated in passive service bands without causing harmful interference to passive services, and the Commission concurs with Marcus, Boeing, and Battelle that such conventional experimental use should be permitted to continue under some circumstances. The Commission observes that in those instances in which an experimental applicant had requested use of a passive band, OET staff in coordination with NTIA undertook a case-by-case review of the application and imposed specific conditions on the applicant, as warranted, to minimize the potential that the experiment would cause harmful interference to passive service(s) that use that band. The Commission therefore finds generally appropriate Marcus's recommended new language for § 5.85(a) that would continue to permit conventional ERS use of the passive bands under limited circumstances, and further modifies the language to also permit compliance testing licensees to use those bands.

Medtronic Petition

6. A medical testing experimental radio license (medical testing license) is issued to hospitals and health care institutions that demonstrate expertise in testing and operation of experimental medical devices that use wireless telecommunications technology or communications functions in clinical trials for diagnosis, treatment, or patient

monitoring. These licenses are for testing medical devices that would operate under existing rules and use radio frequency (RF) wireless technology for diagnosis, treatment, or patient monitoring for the purposes of, but not limited to, assessing patient compatibility and usage issues, as well as operational, interference, and RF immunity issues. Unlike a conventional experimental license, a medical testing license would allow a health care institution to conduct a wide variety of unrelated clinical trials under a single authorization. The Commission will grant authorizations for a geographic area that is inclusive of an institution's real-property facilities where the experimentation will be conducted and that is under the applicant's control. Applications also may specify, and the Commission will grant authorizations for, defined geographic areas beyond the institution's real-property facilities that will be included in clinical trials and monitored by the licensee.

7. Medtronic's petition raises two issues, which the Commission addresses in turn. First, Medtronic asks that the Commission expand the eligibility for the medical testing license. The second issue pertains to cost reimbursement for clinical trials, which is permitted under Food and Drug Administration (FDA) rules. Medtronic requests that the Commission clarify that such reimbursement does not constitute impermissible marketing under §§ 2.803 or 2.805 of its rules. Medtronic asserts that these changes could greatly facilitate clinical trials because the devices would not need to have first been approved by the Commission under its equipment authorization program. No party filed comments regarding any of the issues raised by Medtronic's petition.

8. *Medical testing license eligibility.* Medtronic observes that the *R&O* established this license to meet the needs of the medical community and to allow medical researchers to conduct clinical trials, but limited eligibility for medical testing licenses to health care facilities. Medtronic notes that FDA rules permit a wide range of entities, including non-health care facilities, to sponsor or conduct clinical trial testing. In particular, Medtronic notes that the FDA classifies certain entities involved in medical device research as either ''sponsors'' or ''sponsor-investigators'' of clinical trials, with those terms defined as follows:

Sponsor—A person who initiates, but who does not actually conduct, the investigation, that is, the investigational device is administered, dispensed, or used under the immediate direction of another individual. A person other than an individual that uses one or more of its own employees to conduct an investigation that it has initiated is a sponsor, not a sponsor-investigator, and the employees are investigators.

Sponsor-investigator—An individual who both initiates and actually conducts, alone or with others, an investigation, that is, under whose immediate direction the investigational device is administered, dispensed, or used. The term does not include any person other than an individual. The obligations of a sponsor-investigator under this part include those of an investigator and those of a sponsor.

9. Medtronic observes that under these FDA classifications, a wide-range of entities, including device manufacturers, act as sponsors and sponsor-investigators of clinical trials and engage in real-world patient testing, but that these entities do not always meet the more limited definition of a ''health care facility'' under the Commission's rules. Thus, Medtronic argues, a ''significant portion'' of these entities are not eligible to apply for a medical testing license. These entities, it claims, will be subject to testing limitations and added costs and burdens by having to design their tests to comply with the Commission's other experimental authorization rules (or not be able to conduct them in a manner that provides the most utility for device evaluation purposes). Medtronic asserts that the Commission's licensing structure is inconsistent with FDA regulations that permit a wider variety of entities to sponsor or conduct clinical trial testing, and creates regulatory uncertainty, does not meet the development and testing needs of the medical community, and threatens to frustrate the very innovation that this proceeding is intended to promote. Medtronic also asserts that the new program experimental license (program license) is inappropriate for medical testing because that license does not unreservedly cover clinical trials. Medtronic therefore recommends that the Commission extend the eligibility for medical testing licenses to FDA sponsors and sponsor-investigators of clinical trials involving the testing and operation of new medical devices.

10. Medtronic argues that expanding the eligibility to device manufacturers would level the playing field under the rules since the line between device manufacturers and health care facilities is blurring as healthcare providers are among those who develop medical devices. More specifically, given this overlap between the two with respect to their involvement in developing such devices, Medtronic argues that the following two disparities in regulatory treatment unfairly skew the playing field: (1) Medical testing licensees can operate on frequency bands restricted under § 15.205(a) if the device being tested complies with rules in part 18, part 95, Subpart H (Wireless Medical Telemetry Service), or part 95, Subpart I (Medical Device Radiocommunication Service), but program and conventional experimental licensees cannot; and (2) medical testing licensees can conduct clinical trials outside the physical facilities under their control, but program licensees cannot.

11. The Commission addresses separately in a *Further Notice of Proposed Rulemaking* released simultaneously with this *MO&O,* whether it should permit program licensees to experiment on frequency bands restricted under § 15.205(a), if the device being tested is designed to comply with all applicable service rules in part 18 (Industrial, Scientific, and Medical Equipment), part 95 (Personal Radio Services), Subpart H (Wireless Medical Telemetry Service), or part 95, Subpart I (Medical Device Radiocommunication Service).

12. After careful consideration, the Commission finds good reason to deny Medtronic's request. In the *R&O,* the Commission recognized the importance of its experimental licensing program to the development of RF-based medical devices, and its rules provide a variety of authorizations under which medical device experimentation and clinical trials can be conducted, including program licenses, conventional licenses for market trials, and medical testing licenses. The Commission limited the eligibility and scope of a medical testing license to hospitals and health care institutions to address their particular needs in conducting multiple clinical trials, both within their institutions and at defined geographic areas beyond their facilities that will be monitored by the licensee. This license allows a health care institution to assess patient compatibility and use, as well as operational, interference, and RF immunity issues in real use settings. To accomplish this objective, the medical testing license has elements similar to program licenses and to market trial licenses. As with program licenses, a medical testing licensee can conduct multiple unrelated experiments at its own facility that is under its control. As with market trials, the medical testing licensee can request permission to conduct clinical trials at other specified locations that it monitors. The Commission envisions, for example, that a medical testing license would be helpful to those health care institutions when RF-based medical devices used in clinical trials would be operated

primarily within the institution by hospital staff who can observe how those devices perform in the presence of other RF equipment. In the *R&O,* the Commission recognized that, although a health care facility could oversee a clinical trial beyond its facility, it may not want to assume this responsibility in some cases and instead may prefer that the device manufacturer or health practitioner, under a conventional or market trial license, assume responsibility for clinical trials outside the health care facility.

13. The Commission concludes that if it were to expand eligibility for a medical testing licensee to align with the FDA's regulations, it would undermine the Commission's ability to meet its own objectives. Each agency's rules are designed to satisfy different purposes. The Commission's primary concern in authorizing experimentation with RF devices is to ensure that the devices do not cause harmful interference to authorized users of the spectrum and that the devices do not enter into commerce prior to Commission certification. A part 5 licensee is the party that the Commission holds responsible for the proper operation of the experimental RF devices to avoid harmful interference to authorized spectrum users and to take corrective action as necessary. A part 5 license also specifies the locations for experimentation, *e.g.,* a conventional license would specify the locations where the licensee is conducting experimentation, and a program license limits operation to locations directly under the licensee's control. The FDA's Investigational Device Exemption (IDE) rules cited by Medtronic are designed for a different purpose—to determine the safety or effectiveness of a medical device. To accomplish this objective, the FDA's regulations allow for different categories of participation in clinical trials (*e.g.,* sponsors who initiate, investigators who conduct trials, and sponsor-investigators who take on both roles). A sponsor does not necessarily conduct the investigation, and thus would not be directly responsible for the operation of the experimental RF-based devices as intended by the Commission's part 5 rules. Numerous investigators may conduct the clinical trials, often at a variety of locations which are not required to be, and most likely are not, under the sponsor's control. The Commission is concerned that allowing an FDA sponsor or sponsor-investigator to hold a medical testing experimental license would create confusion in determining who is responsible for the proper operation of the experimental RF devices to avoid harmful interference to other spectrum users and to take corrective action as necessary. Also, trials may be conducted by multiple investigators who are not licensees at many different locations that would not be under the licensee's control. This would be contrary to the basic principles underlying the experimental licensing program. The Commission emphasizes that any health care facility that wishes to be eligible for grant of a medical testing license must meet all eligibility requirements contained in its rules, including the requisite RF expertise.

14. The Commission finds it better serves the public interest to maintain the structure that it adopted, wherein a medical testing license is available only to a qualified health care facility that is solely responsible for clinical trials within its institution. The key element here is that the licensee controls the facility—and hence the interference environment—where multiple clinical trials are being conducted. The medical testing license is designed to address the particular needs of health care institutions in conducting multiple clinical trials within its institution under real use conditions, whether the RF-based medical devices being tested are manufactured by themselves or other manufacturers. To expand eligibility for this license to any manufacturer of medical devices, the Commission would have to identify the real-property facilities that they control and where clinical trials would be conducted. It seems unlikely that a manufacturer would conduct clinical trials at its manufacturing facility if this does not provide real use conditions. Moreover, Medtronic does not ask to conduct clinical trials at its own facilities but rather to conduct such trials at multiple other locations as approved under FDA rules on a trial-by-trial basis. This is fundamentally different than how the medical testing license is intended to operate.

15. In declining to modify the rules as requested by Medtronic, the Commission notes that the part 5 rules provide other options for conducting clinical trials that other entities, such as sponsors, investigators and medical device manufacturers, can use. First, entities may evaluate product performance of an experimental wireless medical device under a market trial by obtaining a conventional experimental license. Typically, market trials are conducted prior to the production stage to evaluate product performance and customer acceptability under expected use conditions. As with medical testing licenses, market trials are authorized for devices that are designed to comply with existing Commission rules. However, unlike a regular conventional experimental license, a market trial license can be used to conduct clinical trials in locations not under the licensee's direct control, such as at a patient's home. Second, for instances where a party is developing a device that would not be able to be operated in compliance with existing rules, the Commission envisioned that such devices can be tested under a conventional experimental license. In summary, manufacturers of medical devices, whether associated with a health care facility or not, would have similar opportunities for experimenting with such devices even though they may do so under different types of authorizations. Both health care institutions that qualify for a medical testing license and device manufacturers that do not must obtain either a program or conventional experimental license to conduct basic research and experimentation. Device manufacturers that do not qualify for a medical testing license would need to obtain a market trial license to conduct clinical trials, which provides more flexibility than a medical testing license for specifying the area(s) within which the trial will be conducted. Health care facilities that qualify for a medical testing license could conduct clinical trials under either a medical testing license or a market trial license. Under the medical testing license, the licensee is limited to areas close to the licensee's own facility, and if it wants to conduct a clinical trial in a location not specified in its license, it would do so under a market trial license.

16. Also, as acknowledged by Medtronic, the Commission may declare a specific geographic area an innovation zone for the purpose of conducting a clinical trial. Such a declaration, which could be made on the Commission's own motion or in response to a public request—such as from a health care facility lacking the RF expertise necessary for obtaining a medical testing licensee—would permit the Commission to designate a defined geographic area and frequency range(s) for specific types of experiments by program licensees within guidelines that the Commission may establish on a case-by-case basis. These innovation zones can include geographic areas beyond a program licensee's authorized area without the licensee having to apply for a new license to cover a new location. Thus, they can serve to effectively extend a program license

without the licensee being required to modify its license to cover a new location. Accordingly, innovation zones will provide opportunities for program licensees, including FDA sponsors and sponsor-investigators, to test potentially innovative wireless devices in real world operating environments, such as testing medical devices in health care institutions. In the *R&O,* the Commission stated that this approach ''may be particularly useful for manufacturers who want to test medical or other types of equipment that will be used in a health care setting while it is in the product development stage, but who will not be eligible for the medical testing license. A manufacturer of medical devices would be able to continue its product testing for clinical trials under its program license at a designated innovation zone without having to apply for a separate market trial license.''

17. As the Commission concluded in the *R&O,* the different licensing options represent a multi-faceted approach to facilitate robust medical RF experimentation that responds to the record developed in this proceeding. The medical testing experimental license complements the types of medical RF experimentation that parties will be able to conduct under a conventional, program, or market trial experimental license. Accordingly, the Commission discovered that limiting eligibility for a medical testing license to hospitals and health care facilities is not detrimental to medical innovation and product development. The Commission's goal in this proceeding is to facilitate bringing ground-breaking new technologies and services to consumers more rapidly, and it finds that its current rules provide the proper incentives toward achieving that goal to both FDA-approved sponsors/sponsor-investigators and to health care facilities. Accordingly, the Commission denies Medtronic's request to expand the eligibility for the medical testing license at this time. As licensees take advantage of the new flexible licenses, the Commission will gain valuable insight as to whether it could modify the rules in the future without sacrificing its objective of ensuring that each clinical trial is conducted in a way that minimizes the potential for harmful interference to authorized services.

18. *Cost reimbursement for clinical trials.* The second issue raised by Medtronic pertains to cost reimbursement for clinical trials of experimental medical devices. Medtronic explains that, while manufacturers of medical devices are not permitted by the FDA to profit from clinical trials, they are allowed to recover certain manufacturing, research, development and handling costs associated with FDA-defined ''investigational devices.'' Medtronic further states that the FDA typically allows sponsors to charge investigators for such devices, and that the costs are usually passed on to the clinical trial subjects. The FDA rules permit a sponsor or investigator to charge subjects for an investigational device, but those entities may not commercialize that device by charging a price larger than that necessary to recover the costs of manufacture, research, development, and handling. Medtronic requests that the Commission clarify that such reimbursement does not constitute impermissible marketing under §§ 2.803 or 2.805 of its rules. Medtronic argues that the requested clarification will ensure consistency between the regulatory regimes of the Commission and the FDA, simplify manufacturers' compliance, and encourage medical device testing and innovation. Medtronic maintains that the purposes of FDA's cost recovery mechanism align with the Commission's marketing restrictions, and that permitting cost recovery in clinical trials will encourage medical device research and development that will ultimately benefit consumers.

19. The Commission's rules generally prohibit the operation and marketing of RF products prior to equipment authorization except under certain specified conditions. § 2.805 (''Operation of radio frequency devices prior to equipment authorization'') lists conditions under which RF devices may be operated prior to equipment authorization, including operation under an experimental radio license issued under part 5 of the rules, and states that an RF device that may be operated prior to equipment authorization ''may not be marketed (as defined in § 2.803(a)) except as provided elsewhere in this chapter.'' § 2.803 (''Marketing of radio frequency products prior to equipment authorization'') defines marketing as ''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.'' These restrictions on marketing are intended to prevent the unchecked dissemination of experimental devices into the stream of commerce, where they may not always be easily recalled. The Commission concludes here that accepting reimbursement payments under the FDA's rules for the use of an unauthorized RF device in a clinical trial falls within this definition of ''marketing.'' However, § 2.803 includes a number of exceptions to the general prohibition against marketing unauthorized equipment. One of those exceptions is for market trials conducted under a part 5 experimental license. Accordingly, and, as explained below, the Commission clarifies that the marketing advocated by Medtronic is permitted on a limited basis under the § 2.803 exception for market trials conducted by part 5 experimental licensees.

20. In the *R&O,* the Commission modified its part 5 rules to provide more flexibility for market trials, including some forms of cost recovery, while continuing to provide safeguards to protect the public. Section 5.602 (''Market Trials'') permits marketing of devices (as defined in § 2.803) and provision of services for hire prior to equipment authorization, provided that the devices included in the market trial are authorized under this rule section and will be operated 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. The rule stipulates that the experimental licensee must own all transmitting and/or receiving equipment, but also permits the experimental licensee to: (1) Sell equipment to other licensees (*e.g.* manufacturer to licensed service provider), and (2) lease equipment to trial participants for purposes of the study. Equipment must be retrieved or rendered inoperable after the trial.

21. The Commission finds that, for devices that necessitate an experimental license for the conduct of a clinical trial, the market trial rule allows for some cost recovery for investigational devices used in those trials consistent with the Commission's purpose to prevent the unchecked dissemination of experimental devices into the stream of commerce. While the Commission's market trial rules differ from the FDA rules, they do provide manufacturers of experimental medical devices a mechanism for offsetting costs associated with the development of those devices. For example, FDA rules allow sponsors to charge investigators for medical devices and these costs may be passed on to the clinical trial participants, and a part 5 market trial licensee may sell devices to another licensee (*e.g.,* a health care facility that is a medical testing licensee) or lease medical devices to trial participants, which may permit full or partial cost

recovery. The Commission believes that this structure generally accommodates Medtronic's request, and serves the public interest by providing medical device manufacturers an incentive to develop innovative, but potentially costly, devices for use in clinical trials.

22. The Commission also observes that not all clinical trials occur under part 5 experimental rules. The Commission's experience has been that clinical trials, especially those involving implanted devices which cannot be easily returned to the licensee as the rules require, occur after the FCC has issued an equipment authorization grant for the device. In those cases, there is no FCC marketing restriction that conflicts with FDA rules.

23. The Commission also clarifies that a medical testing licensee conducting clinical trials that wants to seek reimbursement under the FDA's rules should follow the requirements for market trials in § 5.602. In establishing the medical testing license, the Commission observed that the license will allow for ''clinical trials of medical devices that have already passed through the early developmental stage and are ready to be assessed for patient compatibility and use, as well as operational, interference, and RF immunity issues in real world situations.'' This is conceptually analogous to a market trial, which ''com[es] later in the development process'' and is a ''program designed to evaluate product performance and customer acceptability prior to the production stage.'' Also, both medical testing licenses and market trials licenses are used for devices that will be operated 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. In the *R&O* the Commission stated that it would require a market trial to be authorized under a conventional, rather than a program, license ''in recognition of the inherent difference between market trials and 'regular' experimentation and testing—the most prominent difference being the necessity to prevent an experimental licensee from creating a *de facto* service through the experimental licensing process.'' As discussed above, clinical trials are analogous to market trials, and should be treated like market trials for cost recovery purposes by the experimental license rules. Accordingly, the Commission modifies § 5.402 to make clear that medical testing licensees may recover their costs to the extent they are permitted by the market trial rule.

24. The Commission also clarifies that, under a conventional license issued for a product development trial, a licensee conducting a clinical trial could not be reimbursed for its costs, and the Commission takes this opportunity to correct a contradiction in its current rules regarding product development trials. Although § 2.803 exempts product development trials from the marketing rule for equipment operated prior to certification, the product development trial rule (§ 5.601) expressly prohibits marketing of devices as defined in § 2.803 or the provision of services for hire. This prohibition in the rule is consistent with the Commission's statement in the *R&O* that licensees conducting a product development trial must not market devices or offer services for hire. The Commission differentiated product development trials, which occur very early in the development process, from market trials for marketing purposes. Market trials, which occur later in the development process, can engage in marketing activity if they use equipment that could be operated 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. Product development trials have no such restrictions and thus restricting marketing is important to prevent the unchecked dissemination of experimental devices into the stream of commerce. Clearly, the Commission's intent was to prohibit marketing for product development trials and erred in its drafting of the marketing exceptions in § 2.803. Accordingly, the Commission herein corrects § 2.803(c)(1) to refer only to market trials and remove the reference to product development trials. Thus, the Commission notes that reimbursement under the FDA's rules for clinical trials would not be permitted for a product development trial.

25. Thus, the Commission concludes that Medtronic's requests are best accommodated under the existing rules. To the extent that cost recovery for medical devices used in clinical trials is done under the market trial rules set forth in § 5.602, the Commission grants Medtronic's request and clarifies that such cost recovery does not constitute impermissible marketing under §§ 2.803 and 2.805 of its rules.

Sirius XM and EchoStar Petition

26. In their petition, Sirius XM and EchoStar request that the Commission add a definition of ''emergency notifications'' to its rules to clarify that all participants in the Emergency Alert System are emergency notification providers, and are therefore entitled to notification of program experiments that might affect them, as well as protection from harmful interference that such experiments might cause to them. The *R&O* specified that for program license experiments that may affect critical service bands (*i.e.* bands used for the provision of commercial mobile services, emergency notifications, or public safety purposes), the program licensee must take the additional steps of developing a specific plan to avoid causing harmful interference to operations in those bands prior to commencing operations and providing notice to those critical service licensees who might be affected by the planned experiment.

27. Sirius XM and EchoStar observe that the *NPRM* explicitly recognized that EAS participants provide emergency notifications, and that the *R&O* required that any program licensee seeking to undertake an experiment in a band used for emergency notifications must develop a plan to avoid interference to emergency notification providers, but that the *R&O* failed to specify that such providers include all EAS participants. Sirius XM and EchoStar contend that this failure will create confusion on the part of program license applicants and undermine the Commission's goal of avoiding interference threats to the EAS network. Therefore, to avoid the possibility that program licensees may fail to notify EAS participants of their planned experiments or cause harmful interference to EAS participants, Sirius XM and EchoStar recommend that the Commission set forth a definition of emergency notification providers that includes all EAS participants. No party filed comments regarding the Sirius XM/EchoStar Petition.

28. The Commission's goal throughout this proceeding has been to foster new experimental uses of the RF spectrum, while protecting authorized radio services from any harmful interference that these new uses might cause. Moreover, the Commission has recognized that an additional measure of protection must be afforded to bands used by services that are crucial to the public safety and well-being. The Commission's clear intent in this proceeding has been to include all EAS participants as emergency notification providers. For example, the Commission included this discussion in the *NPRM*: ''. . . Television and radio broadcast bands are used in support of the

Emergency Alert System (EAS). In recognition of these vital interests, the Commission proposes to require that, for tests that affect bands use for the provision of commercial mobile services, emergency notifications, or public safety purposes on the institution's grounds, the licensee first develop a specific plan that avoids interference to these bands.'' As Sirius XM and EchoStar observe, the *R&O* adopted the *NPRM's* proposal that the program licensee must develop a specific plan to avoid harmful interference to operations in these critical service bands, but failed to explicitly state that emergency notification providers include all EAS participants. Accordingly, and to avoid any confusion, the Commission is adding to § 5.5 of the rules a definition of emergency notification providers as inclusive of all EAS participants.

29. *Regulatory Flexibility Certification.* The Regulatory Flexibility Act (RFA) requires that agencies prepare a regulatory flexibility analysis for notice-and-comment rulemaking proceedings, unless the agency certifies that ''the rule will not have a significant economic impact on a substantial number of small entities.'' The Commission hereby certifies that the rule revisions set forth herein will not have a significant economic impact on a substantial number of small entities for the following reasons: (1) The modification of § 5.85(a) essentially restores that rule to what existed prior to initiation of this proceeding, but with the further modification that permits use of passive service bands by compliance testing licensees, as was explicitly authorized in the *R&O.* As explained above, the prohibitions adopted in the rules appendix of the *R&O* was over-inclusive—the stated intent in this proceeding was to prohibit experimental use of the passive bands only by program and medical testing licensees and in product development and market trials. Restoring the rule to allow for the grant of conventional experimental licenses that use the passive bands, which had been permitted for many years prior to adoption of the *R&O,* as well as permitting use of these bands by new compliance testing licensees, will not have an adverse impact on any small entities. (2) Denying FDA sponsors and sponsor-investigators eligibility for medical testing licenses in § 5.402 of the Commission's rules will not adversely impact small entities, as they will still have the ability to conduct clinical medical trials under the auspices of a product development trial, or under a program license in cases in which the Commission establishes an innovation zone for a clinical trial. (3) Clarifying that some cost reimbursement for medical devices used in clinical trials is permissible under the § 5.602 market trial rules may benefit some small entities, without adversely impacting any such entities. (4) Clarifying in § 5.5 of the rules that all participants in the Emergency Alert System are emergency notification providers simply codifies what was adopted in the *R&O,* and will not adversely impact any small entities. The Commission will send a copy of this *Memorandum Opinion and Order,* including this certification, to the Chief Counsel for Advocacy of the Small Business Administration.

30. *Paperwork Reduction Act Analysis.* This document contains no new or modified information collection requirement that are subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. The Commission notes that pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4), it previously sought specific comment on how it might further reduce the information collection burden for small business concerns with fewer than 25 employees.

31. *Congressional Review Act.* The Commission will send a copy of this *Memorandum Opinion and Order* in a report to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

Ordering Clauses

32. Pursuant to section 4(i), 301, 303 and 405 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 301, 303, and 405 and § 1.1, 1.2, and 1.429 of the Commission's rules, 47 CFR 1.1, 1.2, and 1.429, this *Memorandum Opinion and Order is adopted.*

33. The petitions for reconsideration filed by Marcus Spectrum Solutions LLC; Medtronic, Inc.; and Sirius XM Radio Inc. and EchoStar Technologies Inc. *Are granted*, to the extent indicated above, and otherwise *are denied.*

34. Parts 2 and 5 of the Commission's rules *are amended*, as set forth in the Final Rules. These revisions will be effective September 30, 2015 of this *Memorandum Opinion and Order.*

List of Subject in 47 CFR Part 5

Radio, Reporting and recordkeeping requirements.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR parts 2 and 5 as follows:

PART 2—FREQUENCY ALLOCATIONS AND RADIO TREATY MATTERS; GENERAL RULES AND REGULATIONS

■ 1. The authority citation for part 2 continues to read as follows:

Authority: 47 U.S.C. 154, 302a, 303, and 336, unless otherwise noted.

■ 2. Section 2.803 is amended by revising paragraph (c)(1) to read as follows:

§ 2.803 Marketing of radio frequency devices prior to equipment authorization.

* * * * *

(c) * * *

(1) Activities under market trials conducted pursuant to subpart H of part 5.

* * * * *

PART 5—EXPERIMENTAL RADIO SERVICE

■ 3. The authority citation for part 5 continues to read as follows:

Authority: Secs. 4, 302, 303, 307, 336 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 302, 303, 307, 336. Interpret or apply sec. 301, 48 Stat. 1081, as amended; 47 U.S.C. 301.

■ 4. Section 5.5 is amended by adding a definition in alphabetical for ''emergency notification providers'' to read as follows:

§ 5.5 Definition of terms.

* * * * *

Emergency notification providers. All participants in the Emergency Alert System, as identified in section 11.1 of this chapter.

* * * * *

■ 5. Section 5.85 is amended by revising paragraph (a) to read as follows:

§ 5.85 Frequencies and policy governing their assignment.

(a)(1) Stations operating in the Experimental Radio Service may be authorized to use any Federal or non-Federal frequency designated in the Table of Frequency Allocations set forth in part 2 of this chapter, provided that the need for the frequency requested is fully justified by the applicant. Stations authorized under Subparts E and F are subject to additional restrictions.

(2) Applications to use any frequency or frequency band exclusively allocated to the passive services (including the radio astronomy service) must include an explicit justification of why nearby bands that have non-passive allocations are not adequate for the experiment. Such applications must also state that the applicant acknowledges that long term or multiple location use of passive bands is not possible and that the applicant intends to transition any long-term use to a band with appropriate allocations.

* * * * *

■ 6. Section 5.402 is amended by adding paragraph (c) to read as follows:

§ 5.402 Eligibility and usage.

* * * * *

(c) Marketing of devices (as defined in § 2.803(a) of this chapter) is permitted under this license as provided in § 5.602.

[FR Doc. 2015–21295 Filed 8–28–15; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

[Docket No. 141009847–5746–02]

RIN 0648–XD558

Pacific Island Fisheries; 2015 Annual Catch Limits and Accountability Measures

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final specifications.

SUMMARY: In this final rule, NMFS specifies the 2015 annual catch limits (ACLs) for Pacific Island bottomfish, crustacean, precious coral, and coral reef ecosystem fisheries, and accountability measures (AMs) to correct or mitigate any overages of catch limits. The ACLs and AMs support the long-term sustainability of fishery resources of the U.S. Pacific Islands.

DATES: The final specifications are effective September 30, 2015, through December 31, 2015.

ADDRESSES: Copies of the fishery ecosystem plans are available from the Western Pacific Fishery Management Council (Council), 1164 Bishop St., Suite 1400, Honolulu, HI 96813, tel 808–522–8220, fax 808–522–8226, or *www.wpcouncil.org.* Copies of the environmental assessments and findings of no significant impact for this action, identified by NOAA–NMFS–2013–0156, are available from *www.regulations.gov,* or from Michael D. Tosatto, Regional Administrator, NMFS Pacific Islands Region (PIR), 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818.

FOR FURTHER INFORMATION CONTACT: Jarad Makaiau, NMFS PIRO Sustainable Fisheries, 808–725–5176.

SUPPLEMENTARY INFORMATION: NMFS is specifying the 2015 ACLs and AMs for bottomfish, crustacean, precious coral, and coral reef ecosystem fishery management unit species (MUS) in American Samoa, Guam, the CNMI, and Hawaii. NMFS proposed these specifications on July 21, 2015 (80 FR 43046), and the final specifications do not differ from those proposed. The 2015 fishing year began on January 1 and ends on December 31, except for precious coral fisheries, for which the fishing year began on July 1, 2015, and ends on June 30, 2016.

NMFS is not specifying ACLs for MUS that are currently subject to Federal fishing moratoria or prohibitions. These MUS include all species of gold coral, the three Hawaii seamount groundfish (pelagic armorhead, alfonsin, and raftfish), and deepwater precious corals at the Westpac Bed Refugia. The current prohibitions on fishing for these MUS serve as the functional equivalent of an ACL of zero.

Additionally, NMFS is not specifying ACLs for bottomfish, crustacean, precious coral, or coral reef ecosystem MUS identified in the Pacific Remote Islands Area (PRIA) FEP. This is because fishing is prohibited in the EEZ within 12 nm of emergent land of the PRIA, unless authorized by the U.S. Fish and Wildlife Service (USFWS), in consultation with NMFS and the Council. Additionally, there is no suitable habitat for these stocks beyond the 12-nm no-fishing zone, except at Kingman Reef, where fishing for these resources does not occur. To date, the USFWS has not consulted with NMFS for any fishing that the USFWS may authorize within 12 nm of the PRIA. NMFS will continue to monitor authorized fishing within 12 nm of the PRIA in consultation with the USFWS, and may develop additional fishing requirements, including catch limits for species that may require them.

NMFS is also not specifying ACLs for pelagic MUS at this time, because NMFS previously determined that pelagic species are subject to international fishery agreements or have a life cycle of approximately 1 year and are, therefore, statutorily excepted from the ACL requirements.

2015 Annual Catch Limit Specifications

Tables 1–4 list the ACL specifications for 2015.

TABLE 1—AMERICAN SAMOA

Fishery	Management unit species	ACL Specification (lb)
Bottomfish	Bottomfish multi-species stock complex	101,000
Crustacean	Deepwater shrimp	80,000
	Spiny lobster	4,845
	Slipper lobster	30
	Kona crab	3,200
Precious Coral	Black coral	790
	Precious corals in the American Samoa Exploratory Area	2,205
Coral Reef Ecosystem	*Selar crumenophthalmus*—atule, bigeye scad	37,400
	Acanthuridae—surgeonfish	129,400
	Carangidae—jacks	19,900
	Carcharhinidae—reef sharks	1,615
	Crustaceans—crabs	4,300
	Holocentridae—squirrelfish	15,100
	Kyphosidae—rudderfishes	2,000
	Labridae—wrasses	16,200