frequency of performance drills regarding operation of exits in the normal and emergency modes on that type aircraft.

(D) The substitute pilot or flight engineer is in possession of all items required for duty.

(E) The substitute pilot or flight engineer is located in the passenger cabin.

(F) The substitute pilot or flight engineer is identified to the passengers.

(G) The substitution of a pilot or flight engineer for a required flight attendant does not interfere with the safe operation of the flight.

(H) The airplane engines are shut down.

(I) At least one floor-level exit remains open to provide for passenger egress.

(b) During passenger deplaning, on each airplane for which more than one flight attendant is required by § 121.391, the certificate holder may reduce the number of flight attendants required by that paragraph provided:

(1) The airplane engines are shut down;

(2) At least one floor level exit remains open to provide for passenger egress; and

(3) The number of flight attendants on board is at least half the number required by § 121.391, rounded down to the next lower number in the case of fractions, but never fewer than one.

(c) If only one flight attendant is on the airplane during passenger boarding or deplaning, that flight attendant must be located in accordance with the certificate holder's FAA-approved operating procedures. If more than one flight attendant is on the airplane during passenger boarding or deplaning, the flight attendants must be evenly distributed throughout the airplane cabin, in the vicinity of the floor-level exits, to provide the most effective assistance in the event of an emergency.

(d) The time spent by any crewmember conducting passenger boarding or deplaning duties is considered duty time.

Issued in Washington, DC, on October 28, 2010.

**J. Randolph Babbitt,**

*Administrator, Federal Aviation Administration.*

[FR Doc. 2010–28056 Filed 11–4–10; 8:45 am]

**BILLING CODE 4910–03–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 15 CFR Part 902

### 50 CFR Part 665

**[Docket No. 0907211157–0522–04]**

**RIN 0648–AX76**

## Fisheries in the Western Pacific; Community Development Program Process

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

**ACTION:** Final rule; effectiveness of collection-of-information requirements.

**SUMMARY:** In this rule, NMFS announces approval by the Office of Management and Budget (OMB) of collection-of-information requirements contained in regulations implementing Amendment 1 to the Fishery Ecosystem Plans for American Samoa, Hawaii, the Mariana Archipelago, and Western Pacific Pelagic Fisheries, relating to the community development plan process. The intent of this final rule is to inform the public that OMB has approved the associated reporting requirements.

**DATES:** New 50 CFR 665.20(c), published at 75 FR 54044 (September 3, 2010), has been approved by OMB and is effective on December 6, 2010. The amendment to 15 CFR part 902 in this rule is effective December 6, 2010.

**ADDRESSES:** Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this final rule may be submitted to NMFS, attention Michael D. Tosatto, 1601 Kapiolani Blvd., Honolulu, HI 96814, and to OMB by e-mail to *OIRA_Submission@omb.eop.gov* or fax to 202–395–7285.

**FOR FURTHER INFORMATION CONTACT:** Jarad Makaiau, NMFS Pacific Islands Region (PIR), Sustainable Fisheries, tel 808–944–2108.

**SUPPLEMENTARY INFORMATION:** A final rule for Amendment 1 was published in the **Federal Register** on September 3, 2010 (75 FR 54044). The requirements of that final rule, other than the collection-of-information requirements, were effective on October 4, 2010. Because OMB had not approved the collection-of-information requirements by the date that final rule was published, the effective date of the associated permitting and reporting requirements in that rule was delayed. OMB approved the collection-of-information requirements contained in the final rule on September 22, 2010.

Under NOAA Administrative Order 205–11, dated December 17, 1990, the Under Secretary for Oceans and Atmosphere has delegated authority to sign material for publication in the **Federal Register** to the Assistant Administrator for Fisheries, NOAA.

### Classification

This final rule has been determined to be not significant for purposes of Executive Order 12866.

Notwithstanding any other provision of the law, no person is required to respond to, and no person shall be subject to penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act (PRA), unless that collection of information displays a currently valid OMB control number.

This final rule contains new collection-of-information requirements subject to the PRA under OMB Control Number 0648–0612. The public reporting burden for developing and submitting a development plan is estimated to average six hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection information. Send comments regarding these burden estimates or any other aspect of this data collection, including suggestions for reducing the burden, to NMFS (*see* **ADDRESSES**) and to OMB by e-mail to *OIRA_Submission@omb.eop.gov* or fax to 202–395–7285.

### List of Subjects in 15 CFR Part 902

Reporting and recordkeeping requirements.

Dated: November 2, 2010.

**Samuel D. Rauch III,**

*Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.*

■ For the reasons set out in the preamble, 15 CFR part 902 is amended as follows:

## PART 902—NOAA INFORMATION COLLECTION REQUIREMENTS UNDER THE PAPERWORK REDUCTION ACT: OMB CONTROL NUMBERS

■ 1. The authority citation for part 902 continues to read as follows:

**Authority:** 44 U.S.C. 3501 *et seq.*

■ 2. In § 902.1, amend the table in paragraph (b), under the entry "50 CFR"

by adding the entry for § 665.20 in numerical order to read as follows:

**§ 902.1 OMB control numbers assigned pursuant to the Paperwork Reduction Act.**

(b) * * *

* * * * *

| CFR part or section where the information collection requirement is located | Current OMB control No. (all numbers begin with 0648–) |
|---|---|
| * * * * * * * | |
| 50 CFR | |
| * * * * * * * | |
| 665.20 | –0612 |
| * * * * * * * | |

[FR Doc. 2010–28075 Filed 11–4–10; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 892

**[Docket No. FDA–2008–N–0273]**

## Medical Devices; Radiology Devices; Reclassification of Full-Field Digital Mammography System

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the reclassification of the full-field digital mammography (FFDM) system from class III (premarket approval) to class II (special controls). The device type is intended to produce planar digital x-ray images of the entire breast; this generic type of device may include digital mammography acquisition software, full-field digital image receptor, acquisition workstation, automatic exposure control, image processing and reconstruction programs, patient and equipment supports, component parts, and accessories. The special control that will apply to the device is the guidance document entitled "Class II Special Controls Guidance Document: Full-Field Digital Mammography System." FDA is reclassifying the device into class II (special controls) because general controls along with special controls will provide a reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for this device.

**DATES:** This rule is effective December 6, 2010.

**FOR FURTHER INFORMATION CONTACT:**

Mary Pastel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G304, Silver Spring, MD 20993–0002, 301–796–6887; or

Kyle J. Myers, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, rm. 3118, Silver Spring, MD 20993–0002, 301–796–2533.

**SUPPLEMENTARY INFORMATION:**

### I. Statutory Framework for Device Classification

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115), and the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the FD&C Act, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as "preamendments devices." FDA classifies these devices after the Agency has taken the following steps:

1. Receives a recommendation from a device classification panel (an FDA advisory committee);

2. Publishes the panel's recommendation for comment, along with a proposed regulation classifying the device; and

3. Publishes a final regulation classifying the device type.

FDA has classified most preamendments devices under these procedures.

FDA refers to devices that were not in commercial distribution before May 28, 1976, as "postamendments devices." These devices are classified automatically by statute (section 513(f) of the FD&C Act) into class III without any FDA rulemaking process. These device types remain in class III and require premarket approval, unless and until:

1. FDA reclassifies the device type into class I or II;

2. FDA issues an order classifying the device type into class I or II in accordance with section 513(f)(2) of the FD&C Act, as amended by FDAMA; or

3. FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

Reclassification of classified postamendments devices is governed by section 513(f)(3) of the FD&C Act. This section provides that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the FD&C Act, or the manufacturer or importer of a device may petition the Secretary of Health and Human Services (the Secretary) for the issuance of an order classifying the device into class I or class II. FDA's regulations in 21 CFR 860.134 set forth the procedures for the filing and review of a petition for reclassification of these class III devices. To change the classification of the device, the proposed new class must