(b) **Classification.** Class II (special controls). The special controls for this device are:

1. Non-clinical and clinical performance testing must demonstrate the accuracy and reproducibility of the constructed image.
2. Appropriate analysis/testing must validate electromagnetic compatibility, electrical safety, thermal safety, and mechanical safety.
3. Appropriate software verification, validation, and hazard analysis must be performed.
4. All elements of the device that may contact the patient must be demonstrated to be biocompatible.
5. Methods and instructions for reprocessing of any reusable components must be properly validated.
6. The labeling must include specific information needed to ensure proper use of the device.

**Dated:** November 16, 2015.

Leslie Kux, 
Associate Commissioner for Policy.

**POSTAL SERVICE**

39 CFR Part 20

**International Service Changes—** Bonaire, Sint Eustatius, and Saba, Curacao, Netherlands Antilles

**AGENCY:** Postal Service™.

**ACTION:** Final rule.

**SUMMARY:** At the request of the designated operator for Bonaire, Sint Eustatius, and Saba, the Postal Service is adding this country to the Mail Classification Schedule (MCS). The Commission concurred with the notice in its Order No. 2808, issued on November 9, 2015. Documents are available at www.prc.gov, Docket No. MC2016–10. Consequently, the Postal Service will revise IMM sections 213.5, 292.45, 293.45, the Index of Countries and Localities, the Country Price Groups and Weight Limits, and the Individual Country Listings, to add a new listing for Bonaire, Sint Eustatius, and Saba and to modify Curacao’s listing.

**List of Subjects in 39 CFR Part 20**

Foreign relations, International postal services.

Accordingly, 39 CFR part 20 is amended as follows:

**PART 20—[AMENDED]**

1. The authority citation for 39 CFR part 20 continues to read as follows:


2. Revise the following sections of Mailing Standards of the United States Postal Service, International Mail Manual (IMM), as follows:

<table>
<thead>
<tr>
<th>Country labeling name</th>
<th>Foreign office of exchange code</th>
<th>Price group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bonaire, Sint Eustatius, and Saba</td>
<td>BON</td>
<td>17</td>
</tr>
<tr>
<td>Curacao</td>
<td>CUR</td>
<td>17</td>
</tr>
</tbody>
</table>

293 **International Surface Air Lift (ISAL) Service**

293.4 **Mail Preparation**

293.45 **ISAL Foreign Office of Exchange Codes and Price Groups**
### Exhibit 293.45a

**ISAL Foreign Office of Exchange Codes and Price Groups**

*Add a separate listing for Bonaire, Sint Eustatius, and Saba and remove Curacao’s listing as follows:*

<table>
<thead>
<tr>
<th>Country labeling name</th>
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</table>