Topics

- Affirmation of Compliance Codes
  - What they are
  - What they’re used for
  - Importance of accuracy
  - Which codes are required for various FDA regulated products
  - Common errors transmitting
  - Other related data errors
  - Trade responsibility
What they are?

- Codes developed by FDA to be used by ABI filers to provide information useful in expediting review of entries subject to FDA authority.
What are they used for?

- The codes and their qualifiers are used to communicate information about registration, licensing, and approval status of FDA-regulated products.
Importance of Accuracy

- Codes and their qualifiers are now used for more than the manual entry review performed by FDA staff.
- They’re used in automated database look-ups.
- If information transmitted is invalid, the automated database look-up will fail.
AofCs By Center

- CDRH
  - Medical Devices
  - Radiological Health Electronic Products

- CFSAN
  - Low Acid Canned Foods

- CBER - Coming Soon
The process begins with a determination of whether the item is a device or radiological health (RH) product regulated by FDA.

Next, determine the regulatory requirements for importing the device or RH product:
- Requires 510(k), PMA, or is exempt
- Requires RH product and annual reports
- Requires establishment registration and device listing
- Requires compliance with Quality Systems regulation
- Needs impact-resistant lens certification documentation
Medical devices and electronic products

- New affirmation of compliance codes have been created, and the descriptions of some existing codes have been revised.

- For details, see the ACS admin messages to filers which issued on October 9, 2009 - CSMS#09-000324; 9/23/2009 - CSMS#09-000315; 3/18/2010 - CSMS#10-000075; 4/6/2010 - CSMS#10-000097

- Note that affirmations for some electronic products require the filing of a second, related affirmation of compliance.

- **PREDICT**'s automated lookups for medical devices and electronic products will **fail** if the data submitted do not conform to the current codes and definitions.
# Affirmations of Compliance

**Medical device registration numbers**

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEV</td>
<td>Device Foreign Manufacturer Registration Number</td>
<td>The qualifier for this code should be the device registration number issued by CDRH for the firm manufacturing the product identified in the FDA line.</td>
</tr>
<tr>
<td>DFE</td>
<td>Device Foreign Exporter Registration Number</td>
<td>The qualifier for this code should be the device registration number issued by CDRH for the exporter who exports, or offers for export, to the U.S. a device manufactured or processed by another individual, partnership, corporation or association in a foreign country, as well as devices originally manufactured in the United States.</td>
</tr>
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## Affirmations of Compliance

### Medical device registration numbers

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<tr>
<td>DII</td>
<td>Device Initial Importer Registration Number</td>
<td>The qualifier for this code should be the device registration number issued by CDRH for the importer who takes first title to devices imported into the U.S.</td>
</tr>
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</table>
Device Affirmations of Compliance

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<tr>
<td>CPT</td>
<td>Device Component</td>
<td>This code should be used when importing a component of a device that requires further processing or inclusion into the finished device. This code is not to be used if the device is classified by FDA as a finished device, e.g., wheelchair component.</td>
</tr>
<tr>
<td>IDE</td>
<td>Investigational Device Exemption</td>
<td>The qualifier for this code should be the investigational device exemption number issued by CDRH for the product identified in the FDA line.</td>
</tr>
<tr>
<td>IRC</td>
<td>Impact Resistant Lens Certification</td>
<td>This code is used to certify that the filer has on hand the test results or a certificate that shows that the product on the FDA line has met the standard for impact resistance lens.</td>
</tr>
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<tr>
<td>LST</td>
<td>Device Listing Number</td>
<td>The qualifier for this code should be the device listing number issued by CDRH for the product identified in the FDA line.</td>
</tr>
<tr>
<td>LWC</td>
<td>(Electrode) Lead Wire or Patient Cable</td>
<td>This code should be used when importing electrode lead wires, patient cables, or devices that use them. The affirmation means that (1) the device shipment does not contain any pre-wired electrodes, electrode lead wires, or patient (transducer) cables, or (2) any pre-wired electrodes, electrode lead wires or patient cables comply with 21 CFR 898, Performance Standard for Electrode Lead Wires and Patient Cables.</td>
</tr>
<tr>
<td>MDL</td>
<td>Model Number</td>
<td>This code and qualifier should be the manufacturer’s model number or catalog number for the product identified in the FDA line.</td>
</tr>
</tbody>
</table>
# Device Affirmations of Compliance

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<td>PMA</td>
<td>Device Premarket Approval Number</td>
<td>The qualifier is for this code should be the device Premarket Approval (PMA) number, product development protocols (PDP) number or Humanitarian Device Exemption (HDE) number issued by CDRH for the product identified in the FDA line.</td>
</tr>
<tr>
<td>PMN</td>
<td>Device Premarket Notification Number (510(k))</td>
<td>The qualifier for this code should be the device premarket notification (510(k)) number issued by CDRH for the product identified in the FDA line.</td>
</tr>
</tbody>
</table>
Device AofC Examples

- DEV 3003999999 or 9610123 (Note: Should always be the DEV associated with the foreign manufacturer and not US specifications developer)
- DFE 3003999999 or 9710123
- DII 3003999999 or 1021365
- LST  E100100
- PMN K979999
- PMA P979999
## Radiological Health AofCs

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<tr>
<td>ACC</td>
<td>EPRC Accession Number</td>
<td>This code and qualifier should be the Electronic Product Radiation Control (EPRC) product or abbreviated report accession number issued by CDRH for the product identified in the FDA line.</td>
</tr>
<tr>
<td>ANC</td>
<td>EPRC Annual Report Accession Number</td>
<td>This code and qualifier should be the EPRC current annual report (due annually by September 1) accession number issued by CDRH for the product identified in the FDA line.</td>
</tr>
</tbody>
</table>
## Radiological Health AofCs

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| CCM  | EPRC Certifying Component Manufacturer     | This affirmation and qualifier should be used to name the certifying component manufacturer (CCM) of the certified (EPRC) component incorporated in the finished product being imported. As an example, a certified component manufacturer (CCM) can be the maker of laser optical drives (CD/ROM, CD/RW, DVD/ROM, DVD/RW, etc.) incorporated into laptops, computers, fax machines, computer servers, hand-held computers, audio/video end products, boom boxes, entertainment centers, flat screen television products, automobiles, etc. The name of the CCM manufacturer must match the name that appears in the referenced accession number for the laser radiation product report (ACC) and/or annual report (ANC) affirmations. This affirmation is only used when the name of the manufacturer of the finished product is different from the name of the certifying component manufacturer. As an example, a certified DVD player made by Star Laser Inc. is incorporated into a laptop manufactured by BB Laptop Company. The import entry declares the manufacturer of the finished product as BB Laptop Company. The data submitted by the broker for the certified (EPRC) component would look like this:  

- **CCM code using a qualifier of “Star Laser, Inc.”**  
- **ACC / ANC** providing the accession number for the laser annual report 0832857-000, which clearly identifies the certified component (EPRC) manufacturer as Star Laser, Inc.  
- **MDL** AIAM-1210  
- **RB1**, and  
- **Product code** RFY (DVD, BluRay) |
### Radiological Health AofCs

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<td>MDL</td>
<td>Model number</td>
<td>This code and qualifier should be the manufacturer’s model number or catalog number for the product identified in the FDA line.</td>
</tr>
<tr>
<td>RA1-RA7,</td>
<td>EPRC Product Declaration</td>
<td>Various declarations regarding compliance or non-compliance of the RH products. Must be used as a stand-alone AofC and not in combination with ACC or ANC.</td>
</tr>
<tr>
<td>RB1-RB2,</td>
<td>xx (FDA 2877)</td>
<td></td>
</tr>
<tr>
<td>RC1-RC2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RD1-RD3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Radiological Health AotC Examples

- ACC 982xxxx, 981xxxx, 988xxxx, 989xxxx
- ANC 093xxxx (no more than two years old)
- RB1
- MDL 65-125
Special Issues to Consider During Importation process

- Consider doing due diligence by verifying that firm is not on an FDA Import alert: [http://www.fda.gov/ForIndustry/ImportProgram/ImportAlerts/default.htm](http://www.fda.gov/ForIndustry/ImportProgram/ImportAlerts/default.htm)

- Be mindful that the Import for Export (IFE) declaration can only be used for products undergoing further processing. It cannot be used for transshipment of finished devices through the United States. It cannot be used to store finished devices intended solely for export in US warehouses. [http://www.fda.gov/ForIndustry/ImportProgram/ImportforExport/default.htm](http://www.fda.gov/ForIndustry/ImportProgram/ImportforExport/default.htm)

- Filer audits and CBP referrals allow FDA to detect cases of improper disclaiming or incorrect declaration of FDA regulated products.

- Supply chain safety is very important to FDA to prevent counterfeit products and illegal goods from entering the US. If you suspect illegal activity on the part of your clients, please report it to FDA and CBP.

- Components, entries from Foreign Trade Zones, American Goods Returned, trade show entries, sample entries and any non-standard entry raise issues within PREDICT and the entire import entry process.
Acidified and low acid canned foods (ALACFs and LACFs)

- **FCE**: Food canning establishment number
- **SID**: Scheduled process identifier number
- **LACF** container dimensions are to be declared in specific data fields (defined as part of the ABI to ACS interface), *not* as affirmations of compliance.
Acidified and low acid canned foods (ALACFs and LACFs)

- Use the appropriate PIC (Process Indicator Code):
  - Use “E” (Commercially Sterile) for most LACF products, including water activity controlled/formulated products.
  - Use “F” (Aseptic) for LACF commercially sterile aseptically packaged products, which may include various low-acid beverages, puddings, baby foods, etc.
Acidified and low acid canned foods (ALACFs and LACFs)

- Use “I” (Acidified) for all acidified products (i.e., products covered under 21 CFR 114).

- Do not use other PICs such as “T” for LACF or for ALACF products.

- The product description for the entry line should match the description of the food as it was given to FDA when the scheduled process was filed.
Acidified and low acid canned foods (ALACFs and LACFs)

- Use the importer’s text description field to supplement the product code description when necessary, for example, to indicate packing media (oil, brine, tomato sauce, etc.) and/or product style (sliced, chopped, etc.), and/or when there is no product code product name that matches the SID food name.
Common errors

- Multiples of the same code are transmitted for a line
- The qualifier transmitted with a code does not represent the information required (e.g. sending an accession number using a REG code)
- Not supplying all codes required
Other data errors

- AofC Qualifier information transmitted in another data field, such as in the Importer’s description field
- LACF can dimensions transmitted in alternate field
Trade Efforts to Expedite FDA Admissibility Decisions

- When MARCS Imports comes online in a District, the quality of the data submitted to FDA will count more than ever.
- Filers need to work closely with importers to ensure data quality.
- Poor data quality or missing data will increase the review time.
FDA Efforts to Aid Trade Community

- Look for common errors in AofC data transmission
- Conduct one-on-one outreach to resolve
- Modify import data systems in attempt to enhance future database look-up processes
Questions?