ACE PGA Required Data Elements and Values for Radiation Emitting Commodities

Program

- Will always be “RAD”

Process

- Will always be “REP” Non-Medical Radiation Emitting Products

Description

- Should be the description as per the Commercial Inv.

Intended Use: Must be populated with one of the below codes unless the product has dual usage. The field would then be left blank.

<table>
<thead>
<tr>
<th>Intended Use Code</th>
<th>Intended Use Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>085.000</td>
<td>For Veterinary Medical Use as a Non-Food Product under Controlled Distribution</td>
</tr>
<tr>
<td>090.000</td>
<td>For Military Use as a Non-Food Product</td>
</tr>
<tr>
<td>100.000</td>
<td>For Personal Use as a Non-Food Product</td>
</tr>
<tr>
<td>110.000</td>
<td>For Public Exhibition or Display as a Non-Food Product</td>
</tr>
<tr>
<td>120.000</td>
<td>For Public Safety Use as a Non-Food Product</td>
</tr>
<tr>
<td>130.000</td>
<td>For Consumer Use as a Non-Food Product</td>
</tr>
<tr>
<td>140.000</td>
<td>For Charitable Organization Use as Non-Food Product</td>
</tr>
<tr>
<td>150.000</td>
<td>For Commercial Processing as a Non-Food Product</td>
</tr>
</tbody>
</table>
155.000 For Commercial Assembly as a Non-Food Product into a medical device
170.000 For Repair of a Non-Food Product
180.000 For Research and Development as a Non-Food Product
270.000 For industrial use as a Non-Food Product
970.000 For Immediate Re-Exportation
980.000 For Other Use

Product Code
- Must enter FDA product code (Ex: 96R--CR)

Constituent Element (CE)
- Will remain blank

Qty of CE
- Will remain blank

UOM of CE
- Will remain blank

Percent of CE
- Will remains blank

Active
- Will remain blank

ISO Produce (Manufacturer/Grower) (2 Digit Alphanumeric Code)
- ISO Country Code for the country the product was produced (Ex: JP for Japan)

For a complete ISO Country Code List, click here
ISO Source (Shipping Country)

- ISO Country Code for the country the product exported from. This field should only be populated if Country of Production is unknown.

Previously Refused ISO

- If the cargo was previously refused from another country, this field must be populated with an ISO Country code

Trade/Brand Name

- Must be entered for all (Ex: Sony Laser Scanner RM2)

Character Description

- Should be the description as per the Commercial Inv.

Full Quantity Breakdown

- Provide packaging and quantity for the item (Ex: 6 Cartons, each carton contains 4 Boxes, each box contains 4 Pieces)

Can Dimensions

- Will remain blank

Anticipated Arrival Date

- Enter the arrival date and time (should default from file data)

Time

- System should default to 08:00

Location

- System should default port of entry
PGA Line Value

- The value associated to the PGA commodity line
  *Must be entered in whole dollars

**Entities Required**

<table>
<thead>
<tr>
<th>Role Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>MF</td>
<td>Manufacturer of Goods</td>
</tr>
<tr>
<td>DEQ</td>
<td>Shipper</td>
</tr>
<tr>
<td>FD1</td>
<td>FDA Importer (Importer of Record)</td>
</tr>
<tr>
<td>DP</td>
<td>Delivered to Party (US party that physically receives the goods)</td>
</tr>
</tbody>
</table>

**List of Affirmation of Compliance Codes**

Some of the commodities in the Radiation Emitting category require [FDA form 2877](#) (Declaration for Imported Electronic Products Subject to Radiation Control Standards). For information on FDA form 2877, click here. These products are:

- Veterinary Therapy Ultrasonic Products
- Cabinet X-Ray Systems, Non Medical
- Cold-Cathode Gas Discharge Tubes
- TV Receivers
- Microwave Ovens
- Data Measurement, Transmit, Control Laser Products
- Laser Light Show/Display Products
- Material Processing Laser Products
• Mercury Vapor Lamps
• Other Demonstrational Laser Products
• Other Laser Products
• Research, Scientific, Laboratory Laser Products
• Safety, Security, Surveillance Laser Products
• Surveying, Leveling, Alignment Laser Products
• Utility/Peripheral Laser Products

Based on the above, **if Form 2877 is required for your commodity, the below AOC’s are required:**

**RA1**

- Enter Date- format MM/YYYY

Statement on form 2877:

1. Were manufactured prior to the effective date of any applicable standard. Date of Manufacture:____________________________

**RA2**

- Example: DOD exemption

Statement on form 2877:

2. Are excluded by the applicability clause or definition in the standard or by FDA written guidance. Specify reason for exclusion:______________

**RA3**
• Only Enter the Qualifier RA3

Statement on form 2877:

3. Are personal household goods of an individual entering the U.S. or being returned to a U.S. resident (Limit: 3 of each product type)

RA4

• Only Enter the Qualifier RA4

Statement on form 2877:

4. Are property of a party residing outside the U.S. and will be returned to the owner after repair or servicing.

RA5*

• Enter description of the end product. (Ex: Laser)

Statement on form 2877:

5. Are components or subassemblies to be used in manufacturing or as replacement parts

RA6

• Only Enter the Qualifier RA6

Statement on form 2877:

6. Are prototypes intended for ongoing product development by the importing firms, are labeled "FOR TEST/EVALUATION ONLY" and will be exported, destroyed, or held for future testing.
there is a quantity limit for this option-stated on the back of the 2877 (page 2)

**RA7***

- Enter Description of End Product

*Statement on form 2877:*

7. Are being reprocessed in accordance with P.L. 104-134 or other FDA guidance, are labeled "FOR EXPORT ONLY" and will not be sold, distributed or transferred without FDA approval.

**RB1***

- If RB1 then ACC (product report accession number) OR ANC (annual report accession number) must be provided.

*Statement on form 2877:*

B1. Comply with the performance standards- 1. Last annual report or Product/Initial Report

**RB2***

- Enter the reason the product complies

*Statement on form 2877:*

B2. Comply with the performance standards-2. Unknown manufacturer/report number. State reason:

**RC1***

- Only Enter the Qualifier RC1
Statement on form 2877:

C1. Do not comply with performance standards; are being held under a temporary import bond; will not be introduced into commerce, will be used under a radiation protection plan, and will be destroyed or exported under U.S. Customs Supervision when the mission is complete - 1. Research, Investigations/Studies, or Training (Attach Form FDA 766)

RC2

- Enter Dates and Use Restriction

Statement on form 2877:

C2. Do not comply with performance standards; are being held under a temporary import bond; will not be introduced into commerce, will be used under a radiation protection plan, and will be destroyed or exported under U.S. Customs Supervision when the mission is complete - 1. Trade Show/Demonstration; List dates and use restrictions

RD1*

- Only Enter the Qualifier RD1

Statement on form 2877:

D1. Do not comply with performance standards; are held and will remain under bond; and will not be introduced into commerce until notification is received from FDA that products have been brought into compliance in accordance with an FDA approved petition. (See Form FDA 766) -1. Approved Petition is attached.
**RD2**

- Only Enter the Qualifier RD2

**Statement on form 2877:**

D2. Do not comply with performance standards; are held and will remain under bond; and will not be introduced into commerce until notification is received from FDA that products have been brought into compliance in accordance with an FDA approved petition. (See Form FDA 766) - 2. Petition request is attached.

**RD3**

- Enter the date form 766 will be provided, due within 60 days of submission.

**Statement on form 2877:**

D3. Do not comply with performance standards; are held and will remain under bond; and will not be introduced into commerce until notification is received from FDA that products have been brought into compliance in accordance with an FDA approved petition. (See Form FDA 766) - 3. Request will be submitted within 60 days.

*Annotates that additional information may be needed at time of entry in order for FDA to make a final admissibility decision.

Should you have any question, concerns or simply wish to discuss this new requirement please feel free to email compliance@shipamerican.com with your inquiry. Otherwise please feel free to contact your Customer Service Representative, Sales Person or your usual contact party.