

From: John Jankovich
To: Eli Port
Date: 10/30/03 9:14AM
Subject: Re: Maquiladoras

Eli,

This is a response to your question regarding how distribution of products from the fabrication facility of Systems Sensors, located in a maquiladora area should be addressed in the sealed source and device (SSD) registration. The following is not an interpretation binding on the Commission, but does reflect the NRC staff's view on the regulation.

I have consulted with the NRC experts for international questions. The conclusion is that the special status of the maquiladora applies to import/export issues only regarding US Customs and its reporting requirements; and that the special status does not apply to NRC requirements. Therefore, Systems Sensors should amend its SSD registration certificate NR-0547-D-101-E to include the fabrication facility in Juarez, Mexico.

Please note that the information regarding fabrication, quality assurance, and record keeping that you have provided in your e-mail dated Sept. 8, 2003, should be essentially sufficient for the NRC to amend the certificate. However, for distribution from the Juarez location, you should emphasize (i.e. reference or enclose) the final QA/QC procedure including the sampling size for the production lots. We intend to reference in the registration certificate the final checks that Systems Sensors will implement for the distribution lots from Juarez.

Please note that we do need a formal request from Systems Sensor for the amendment, your e-mail is not sufficient. The request should come from Systems Sensor with their signature and should present the information that was in your e-mail plus the additional information I described above. There is no fee for an amendment.

If you need further information, please contact me by e-mail or call at 301 415-7904.
John Jankovich

>>> Eli Port <eport@rssinc.org> 10/27/03 03:55PM >>>
John:

Once again, I have been unable to reach you by phone today and, once again, I am resorting to my least favorite form of communication, email. I hope that you will have an answer to this question soon. We have been exploring the issue for several months and System Sensor has pressing needs for an answer to enable making a business decision.

Thanks

Eli

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At 01:51 PM 9/11/03 -0400, John Jankovich wrote:

>Eli,

>I received your e-mail dated Sept. 8, 2003, describing the
>distribution/fabrication plan that Systems Sensors intends to
>implement. I contacted the NRC specialists to interpret how a site in a

>maquiladora should be considered for licensing purposes. I have not
>received an answer yet. I will be out of the office between Sept 12-
>27. I will respond to you when I return. In the meantime, if you need
>something urgently, please contact my manager, Marissa Bailey at
>mgb@nrc.gov or call her at 301 415-7648.

>John J.

>

> >>> Eli Port <eport@rssinc.org> 09/08/03 02:09PM >>>

>John:

>

>I am paraphrasing the second option in your August 20 email. System Sensor
>wishes to establish a distribution center in their maquiladora to
>physically distribute the products, manufactured in the maquiladora, and
>will has a company address in the US. The current commitments in documents
>referenced in their device registration, NR-0547-D-101-E, for product
>manufactured in the maquiladora and distributed from El Paso, Texas or St.
>Charles, Illinois, include:

> * The Juarez, Mexico facility is totally owned and operated by System
>Sensor.

> * The Quality/Control Assurance (QC/QA) Program is the same as the
>program described in our application for registration of the above
>referenced device and applied to activities in St. Charles, Illinois.

> * All production and QC/QA stages are completed in Juarez.

> * Copies of QC/QA records will be forwarded to St. Charles quarterly.

> * All QC/QA records for elements referenced in the application for
>device registration or required by 10 CFR 32 will be available for
>inspection in St. Charles.

> * Records which have not been forwarded at the time of an inspection
>will, upon request, be made available in a timely fashion.

> * All commitments made in support of the application for device
>registration shall apply to products manufactured in Juarez.

> * Product manufactured in Juarez is completed, labeled and packaged in
>Juarez.

> * System Sensor will perform quarterly audits of the Quality Control
>program at its Juarez, Mexico facility. Records of these audits shall be
>retained for inspection at the St. Charles, IL facility.

>Product made in the System Sensor maquiladora currently must be shipped to
>St. Charles, Illinois or El Paso, Texas for distribution. Can the
>registration can be amended to authorize distribution directly from the
>System Sensor maquiladora with the above commitments met. These
>commitments appear to satisfy 10 CFR 110.53(a). Please call me at
>847-965-1999 if you have any questions.

>

>Thank you.

>

>Eli

>Eli Port

>RSSI

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CC: john Li; Marissa Bailey; Neil Pedersen; Thomas Essig

Mail Envelope Properties

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Subject: Re: Maquiladoras
Creation Date: 10/30/03 9:14AM
From: John Jankovich

Created By: JPJ2@nrc.gov

Recipients	Action	Date & Time
nrc.gov		
twf4_po.TWFN_DO	Delivered	10/30/03 09:14AM
MGB CC (Marissa Bailey)	Opened	10/30/03 09:34AM
THE CC (Thomas Essig)		
rssinc.org		
eport (Eli Port)	Transferred	10/30/03 09:15AM
systemsensor.com		
John_Li CC (john Li)	Transferred	10/30/03 09:15AM
Neil_Pedersen CC (Neil Pedersen)		

Post Office	Delivered	Route
twf4_po.TWFN_DO	10/30/03 09:14AM	nrc.gov rssinc.org systemsensor.com

Files	Size	Date & Time
MESSAGE	9490	10/30/03 09:14AM

Options

Auto Delete: No
Expiration Date: None

Notify Recipients:	Yes
Priority:	Standard
Reply Requested:	No
Return Notification:	None
Concealed Subject:	No
Security:	Standard
To Be Delivered:	Immediate
Status Tracking:	Delivered & Opened