

## Bhachu, Ujagar

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**From:** Aric Tillberg <atillber@morphodetection.com>  
**Sent:** Friday, February 08, 2013 11:16 AM  
**To:** Bhachu, Ujagar  
**Cc:** Jankovich, John  
**Subject:** Itemiser 3 Enhanced Amendment Response  
**Attachments:** 02-08-12 I3E (Itemiser 3 Enhanced) Review by NRC – Response Letter to Mr. Ujagar Bhachu.pdf

Dear Mr. Bhachu,

Please find attached a letter in response to the questions you asked during our phone conversation dated January 18<sup>th</sup>, 2013 about our amendment request to change the naming convention of one of our trace detection devices on our NRC Exempt Distribution License. Please contact me if additional information is needed.

Best Regards,

**Aric Tillberg**

Radiation Safety Officer Wilmington/Safety Specialist

**T** +1 978 909 1227  
**M** +1 978 488 6582  
**F** +1 866 248 9105  
Morpho Detection, Inc.  
205 Lowell St.  
Wilmington, MA 01997  
[www.morphodetection.com](http://www.morphodetection.com)





Aric Tillberg  
Radiation Safety Officer-Wilmington  
Safety Specialist  
205 Lowell Street Wilmington, MA 01887 USA  
T +1 (978) 495-6592 F +1 (866) 249-9105

U.S. Nuclear Regulatory Commission  
11555 Rockville Pike  
Rockville, MD 20852

Attn: Mr. Ujagar Bhachu

February 8<sup>th</sup>, 2013

**Subject: I3E (Itemiser 3 Enhanced) Review by NRC – Response Letter to Mr. Ujagar Bhachu**

Dear Mr. Bhachu,

This letter is in response to the questions you asked during our phone conversation on January 18<sup>th</sup>, 2013 about our amendment request to change the naming convention of one of our trace detection devices on our NRC Exempt Distribution License. In our original amendment request dated November 1<sup>st</sup>, 2012 to John Jankovich, we explained in great detail that our device known as I3 (Itemiser 3) had a new naming convention called I3E (Itemiser 3 Enhanced), but that the device itself was not changed in any way that would require a new SSDR review. The I3E is technologically, mechanically, functionally, and radiologically the EXACT same device as its previous version called I3. All internal and external schematics, drawings, physical dimensions, and thus radiological safety properties are the same. The change in name was spawned when it was discovered that we were unable to continue purchasing a part in the I3's computer processor due to discontinuation by the manufacturer of that part. A replacement was found, a flash memory drive added, the Windows operating system was upgraded, and we changed the modern USB from antiquated floppy drive technology. The device continues to be the I3 as it always was; it was simply enhanced with modern computer upgrades that had no material effect on design, use, or operability. The change in name from I3 to I3E was more of a management decision than an engineering decision, and does not reflect a new model. For completeness, we wanted our RAML to show the new name. We wish to replace the label to reflect the new naming convention, but did not want to proceed until the new name appeared on our RAML. Having explained this; let me address each of your questions (in bold face) in turn with our responses in italics:

Morpho Detection, Inc.  
205 Lowell Street  
Wilmington, MA 01887 USA  
[www.morphodetection.com](http://www.morphodetection.com)  
T + 1 800 433 5346 205 F + 1 866 249 9105

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Aric Tillberg  
Radiation Safety Officer-Wilmington  
Safety Specialist  
205 Lowell Street Wilmington, MA 01887 USA  
T +1 (978) 495-6592 F +1 (866) 249-9105

1. **Provide a copy of the I3E label:**
  - a. *The label will be created once we receive our amended RAML approving the new name.*
2. **Is there a difference in serial numbers:**
  - a. *Each device has a unique serial number, regardless of the naming convention for our device.*
3. **Confirm that the serialization structure is in the quality assurance program:**
  - a. *Our quality assurance program has not changed from that which was approved by NRC for the I3.*
4. **Provide the date that we plan on starting the manufacture of the I3E:**
  - a. *The device previously known as I3 is the same device as the I3E. We were no longer able to obtain a computer part due to end of life issues and switched to one that was available. I3E is not a new device; it is a new name for an existing device.*
5. **Provide date that we plan to stop manufacturing I3:**
  - a. *Same answer as #4 above.*
6. **Address the service and exchange protocols of the I3's:**
  - a. *If an I3 is returned for service, it is serviced in the same way described in our original NRC submission. The available computer part is used, as the old part can no longer be obtained.*
  - b. *If a customer wishes to have the end-of-life computer part replaced, the device is serviced with the computer enhancements described.*
7. **How many I3's are currently in use by customers (exact number not needed):**
  - a. *The I3 remains in active use by customers.*
8. **How many I3's are at MDI that have not been sold:**
  - a. *MDI possesses thirty nine (39) I3's that are not for retail sale. These devices are used as loaner device for those customers that have a device in the Wilmington service depot for service and as reference for service personnel to troubleshoot customer's potential issues. The final use of these devices is as an internal reference used to compare current product functionality to the I3.*



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**9. Provide any additional information regarding the transition between the I3 and I3E:**

- a. The I3/I3E transition is simply a change in naming convention when it was discovered that one of the parts in the I3 computer processor was no longer being manufactured. Morpho Detection identified a suitable and more modern replacement part. The device remained the same in every aspect relative to radiation safety and functionality. There were no changes to the user interface, operations, or system performance. With the approval of the name change on our RAML, Morpho Detection will create a new label for the device to reflect the I3E name, and assign a model number.*

I hope that now each of your questions has been addressed. Please do not hesitate to contact me should you have any other questions.

Best Regards,

Aric Tillberg  
Radiation Safety Officer

*Cc. Mr. John Jankovich*

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