



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

January 10, 2000

George Vandrish
Intelligent Detection Systems
152 Cleopatra Drive
Nepean, Ontario
Canada K2G 5X2

Dear Mr. Vandrish:

We have completed a preliminary review of your application dated December 17, 1999, requesting amendment of material license number 54-23849-01E and registration certificate no. NR-1018-D-101-E for the Models Orion and Orion Plus explosive detectors. In reviewing the application, we have found that you need to apply for registration of the Models Orion and Orion Plus devices as new explosive detectors. We understand that the Models Orion and Orion Plus use the previously approved ion mobility spectrum, but a consumer product such as your explosive detector must be registered as a whole unit, not a separate component in accordance with 10 CFR 32.26.

Therefore, we have discontinued the review of your application. This is without prejudice to re-submission of your application. If you decide to re-submit your application for registration and license amendment, please ensure that you have included sufficient information to allow NRC to evaluate your design.

For the registration of your devices we need a complete set of information as specified in the provisions of 10 CFR 30.20 and 32.26. Without full documentation and adequate information, the NRC staff is unable to complete a safety evaluation of your design. Specifically, your application did not address the following issues for the Models Orion and Orion Plus devices:

- Construction of the completed product including engineering drawings, materials, etc.;
- Labeling on the external surface of the completed product, and tamper proofing of its attachment;
- Prototype testing of the completed product for normal use and likely accident conditions;
- Maximum radiation level and commitment for Orion Plus;
- Implementation of your quality assurance program (if you are certified for ISO9001, please provide a copy of the certificate.);
- Acceptance sampling procedures for the completed product.

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You may find NUREG-1556, Volume 3, enclosed for your reference, useful for the preparation of your application. If you have any questions, please call Dr. Seung Lee at (301) 415-5787.

Sincerely,

151

Frederick Sturz, Section Chief
 Materials Safety and Inspection Branch
 Division of Industrial and
 Medical Nuclear Safety
 Office of Nuclear Material Safety
 and Safeguards

Enclosure: As stated

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Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards


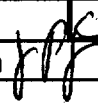

Enclosure: As stated

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REQUEST FOR A SEALED SOURCE OR DEVICE EVALUATION

INSTRUCTIONS: Send this request AND a copy of all related letters/applications and drawings to the Chief, Sealed Source Safety Section, OWFN Mail Stop O-6 H3. Change the License Tracking System milestone to 19 and assign to reviewer code 1-5.
NOTE: Retain a copy of this request with the application and background files.

REQUESTER Intelligent Detection Systems		REGION/LOCATION: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> HQ <input type="checkbox"/> LFARB	
TELEPHONE NUMBER	DATE	TYPE OF ACTION REQUESTED (Check as appropriate)	
NAME OF APPLICANT George Vandish		<input type="checkbox"/> SOURCE REVIEW	<input checked="" type="checkbox"/> AMENDMENT OF REGISTRATION SHEET NUMBER(S)
MAIL CONTROL NUMBER(S)		<input type="checkbox"/> DEVICE REVIEW	<u>NR-1018-D-101-E</u>
LETTER/APPLICATION DATE 12/17/1999	LICENSE NUMBER(S) 54-23849-01E	<input type="checkbox"/> CUSTOM REVIEW	

COMMENTS:
**152 Cleopatra Drive, Nepean, Ontario
Canada K2G 5X2**

FOR SSSS USE ONLY

REVIEWER Seung Lee	MODEL NUMBERS Ion Mobility	NUMBER ASSIGNED 99-66
DATE RECEIVED 12/28/1999	DATE ASSIGNED 12/28/1999	DATE TO FEES 12/28/1999

TYPE OF ACTION (Indicate the number of each type)

<input checked="" type="checkbox"/> COMMERCIAL DISTRIBUTION (FORMAL)		<input type="checkbox"/> USE BY A SINGLE APPLICANT (CUSTOM)	
SOURCE (9C)	DEVICE (9A)	SOURCE (9D)	DEVICE (9B)
<input type="checkbox"/> NEW	<input type="checkbox"/> NEW	<input type="checkbox"/> NEW	<input type="checkbox"/> NEW
<input type="checkbox"/> AMENDMENT	<input checked="" type="checkbox"/> AMENDMENT	<input type="checkbox"/> AMENDMENT	<input type="checkbox"/> AMENDMENT
<input checked="" type="checkbox"/> NO SAFETY EVALUATION REQUIRED NO FEES REQUIRED		<input type="checkbox"/> LICENSING ACTION REQUIRED (IF KNOWN)	<input type="checkbox"/> YES <input type="checkbox"/> NO
<input type="checkbox"/> OTHER (Specify)			
	TOTAL NUMBER OF REVIEW HOURS	NOTES Amendment to NR-1018-D-101-E and License #54-23849-01-E	
	NUMBER OF DEFICIENCY LETTERS		
	NUMBER OF DEFICIENCY CALLS		

FOR FEE USE ONLY

TYPE OF FEE		FEE CATEGORY <input type="checkbox"/> 9A <input type="checkbox"/> 9B <input type="checkbox"/> 9C <input type="checkbox"/> 9D	
AMOUNT RECEIVED	CHECK NUMBER	DATE OF CHECK	LOG
APPROVED BY			DATE OF RETURN
COMMENTS			