

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

SUBJECT: Registration and licensing of the Orion and Orion Plus

Dear Mr. Vandrish:

To summarize our communications thus far, you requested, in your August 17, 1999, facsimile, that we change the name on your registration from explosives detector to organic vapor detector. However, this is not possible since this name change appeared to indicate that the detectors would be used for a purpose other than the protection of life and property from fires and airborne hazards as described by 10 CFR 32.26. Your request to change the name on your registration led to our questions, in our letter of November 24, 1999, on the intended use of your licensed explosive detectors. We were concerned that your intended use was outside the purposes specified in 10 CFR 32.26. In a telephone conversation on December 14, 1999, we discussed a number of issues regarding your various vapor detection instruments. We indicated to you that you should not distribute the Ariel or Sirius instruments, pursuant to 10 CFR 32.26, until we were able to clarify our requirements with respect to your case in regard to the following two issues: (1) distribution of the IMS cell as a component versus distribution of the Orion/Orion Plus as a complete unit, and (2) distribution of drug detectors, and combined drug/explosive detectors. In support of item (1), we asked you to submit an amendment request to increase your instrument activity from 3.3 to 6.6 millicuries, since you explained that the Orion Plus instrument system contained two nickel-63 sources. You sent this request on December 17, 1999. In our letter to you dated January 10, 2000, we advised you that your request for amendment of your registration was rejected for lack of sufficient information to support the registration of the Orion and Orion Plus systems. Your letter of January 17, 2000, indicated that you believed we had all the information needed.

Upon re-examination of the information in the letters and the registration and license files, we believe that additional information is still necessary. In our telephone conversation on March 2, 2000, we discussed the requirements that remain to be addressed with regard to the distribution of the IMS cell as a component versus distribution of the Orion/Orion Plus as complete units. We also discussed the distribution of drug detectors, and combined drug/explosive detectors. In addition, we advised you that the IMS cell must remain inseparable from the Orion and Orion Plus in order for continued use under the exemption. We advised you that in order to repair or replace the IMS cell the entire Orion or Orion Plus instrument system would have to be redistributed by Intelligent Detection Systems in accordance with its exempt distribution license. Another option we mentioned for repair or replacement of the IMS cell was to distribute the Orion and Orion Plus as a generally licensed device. This would allow your service personnel to perform this function at the customer's site.

Regarding the issue of distribution of the IMS cell as a component versus distribution of the Orion/Orion Plus as a complete unit, recent increases in requests for registration of detectors under 10 CFR 32.26 has resulted in a clarification of the regulation. NRC staff recently determined that 10 CFR 32.26 does not allow the exempt distribution of a component of a gas and aerosol detection instrument, e.g., the IMS cell. Incomplete products that cannot function alone as a gas and aerosol detector cannot be registered and licensed for exempt distribution pursuant to 10 CFR 32.26. We have determined (1) that in order to be in compliance with the intent of 10 CFR 32.26, the detector must be registered and distributed as a complete product, and (2) that the radioactive material must not be separable from the complete product.

Since your product was originally registered as a component only, additional information regarding the complete units are needed to allow modification of your registration certificate and distribution license to be in compliance with 10 CFR 32.26 requirements. Please note that some of these items were addressed in our previous telephone conversation with you on December 14, 1999, and in our letter to you dated January 10, 2000. These issues have been repeated here in order to provide a complete list of requirements and clarify the information that is needed.

1. The current registration is for the IMS cell itself. As such, the maximum activity for the cell is listed as 3.3 millicuries. Since the detectors must now be registered as complete products, the registration certificate will have to be modified to refer to the Orion and Orion Plus instead of the IMS cell component. We understand from our previous conversations that the Orion contains one IMS cell, and that the Orion Plus contains two IMS cells. For each of these instrument systems, please submit drawings of the complete systems, including product labeling and indication of where and how the cell(s) is mounted into the device. The drawings must include dimensions, materials, and method of assembly.
2. 10 CFR 32.29 contains specific requirements regarding labeling requirements. Your current registration contains labeling commitments consistent with the registered IMS cell. Modification of the registration will require that the complete instrument (Orion and Orion Plus) be labeled as the registered product. Since testing and radiation information was provided for the cell itself, the cell should retain the current labeling indicating isotope, activity, your company identification, and the radiation symbol.
3. Quality assurance/quality control procedures (QA/QC) as they relate to the Orion and Orion Plus products must be submitted in order to encompass inspections of the complete product. Please clarify the extent these procedures will be the same as those already submitted. In addition, if repair and replacement of the IMS cell will be required, then these operations would require a redistribution of the Orion/Orion Plus in accordance with the NRC license. If repair and replacement of the IMS cell will be required, describe how redistribution QA/QC checks will be performed prior to redistribution to the same customer or a different customer.

Please submit the requested information within 30 days from the date of this letter. Upon receipt of this information, we will review it and contact you regarding any additional information that may be needed to complete modification of the registration and license.

Regarding the issue of distribution of drug detectors, and combined drug/explosive detectors, we have determined that 10 CFR 32.26 does not permit the licensing of a drug detection instrument since it does not protect life and property from fires and airborne hazards as described in 10 CFR 32.26. However, if an explosives detector also coincidentally detects drugs, without the explosives detection function being disabled, then the explosives detection instrument may be licensed pursuant to 10 CFR 32.26. Also, if an instrument contains one IMS cell specifically to detect drugs, even though another IMS cell in the instrument specifically detects explosives, the instrument may not be licensed pursuant to 10 CFR 32.26. For example, it is permissible for the cell to detect both drugs and explosives simultaneously, but it is not permissible for the cell to be "switched" between drugs and explosives, nor could the device contain two separate cells - one for drugs and one for explosives.

In view of the clarifications of 10 CFR 32.26, please confirm the following within 30 days:

1. That your marketing, labeling and instructions regarding the Orion and Orion Plus instrument systems, licensed pursuant to 10 CFR 32.26, will clearly indicate that these instrument systems are designed for explosives detection.
2. That instructions to the user will not discuss disabling the explosive detector function in order to detect drugs using the IMS cell(s).
3. That you will not manufacture or distribute the Model Sirius instrument system pursuant to 10 CFR 32.26, if either of the IMS cells will be used exclusively for drug detection rather than explosives detection.
4. That you will not manufacture or distribute the Model Ariel drug detection system pursuant to 10 CFR 32.26.

If you have any questions, please do not hesitate to contact Anthony Kirkwood of my staff at 301-415-6140 .

Sincerely,

John W. N. Hickey, Chief
 Materials Safety and Inspection Branch
 Division of Industrial and
 Medical Nuclear Safety
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