

## INFORMATION LETTER

FOR DISTRIBUTION TO ALL ECD USERS,  
OWNERS & CARE-TAKERS.

The Authorities have found that many ECD users  
are unaware of ALL the regulatory requirements.

## RADIATION SAFETY OFFICER REQUIREMENTS

The following is a communication generated in response to concerns that the Radiation Authorities have expressed to us. We are making our clients aware of the applicable regulations, to avoid the need for action by the Authorities, with potentially unpleasant and/or costly consequences for those who are not in compliance.

The Radioactive Material Regulations require that all ECD owner Companies assign a care-taker for all Radioactive Material Containing Devices, henceforth called Radiation Safety Officer. The RSO is responsible that all applicable rules are complied with.

1. The RSO must perform surveys at regular intervals to ensure that no Radioactivity has leaked out of the Device and contaminated its exterior surface. To do the Leak-Test, one or more Wipes are taken from the device which are then measured by an authorized Company (distributors of the Wipe-Kit). For most ECDs this test must be performed every 6 months. Only for Varian ECDs an extension to 36 months has been granted. Check with your Local Authority to find out if this extension applies in your area of use.

*(C.J.B. & CO. is an authorized distributor of Wipe-Kits)*

2. The RSO is required to generate an Inventory Report twice a year. These reports, as well as the Leak-Test Records must be made available to a Radiologic Health Inspector who could show up unannounced at any time. The signed and dated Semi-Annual Inventory Report must show the total quantity of ECDs owned by the Company (identified by Manufacturer, Model Nr. and Serial Nr.) and the location where they are in use or stored.

3. Transfers of Control or Ownership of an ECD may occur only through a Specific Licensee authorized to do so. Transfers direct from one General Licensee to another is strictly forbidden. C.J.B. & CO. has a Specific License giving us authorization to service and distribute all brands of ECDs. Our License also allows us to give assistance when transfers to other General Licensees are needed. We inform the Authorities and supply both parties with a Transfer Certificate. We charge \$100.00 for the documentation plus Freight and \$25.00 for the mandatory Survey.

\*Distribution (or legal transfer) of a Generally Licensed Device requires registration. Owners become General Licensees.

4. The RSO must make sure that ECDs are discarded of in an authorized manner. This can only be done by a Licensed Company. C.J.B. & CO. is licensed to assist in the Relinquish of Ownership of Ni63 ECDs. C.J.B. & CO. provides its Clients with an Relinquish of Ownership Certificate. The RSO must keep these on file with the Company Inventory Records. In case the Company plans to discontinue all ECD use, the Disposal and / or Transfer Certificate must be mailed to the Radiation Authority with a letter expressing that intention.

5. In case of Loss, Damage or Contamination, the Radiation Authority requires the RSO to report the event(s) and planned action immediately after discovery by phone and by registered mail.
6. The RSO must report changes in location-of-use or storage prior to it taking place. For ECDs placed on GCs in mobile units this requirement refers to a move of home-base. Rules regarding temporary work-sites may vary at different locations and should be checked with the Radiation Control Authorities which have jurisdiction in the different locations.
7. The RSO must be in possession of the (manufacturer) supplied ECD Radiation Safety Manual and must be familiar with it's content. For sections applicable in 10CFR or other Agreement State Regulations, please consult your local Radiation Authority.

**PLEASE CALL C.J.B. & CO. IF YOU HAVE ANY ECD RELATED QUESTIONS.**

**800-252-7896 - 360-671-0182**