

**From:** Bryan Parker  
**To:** Dwyer, James  
**Date:** 2/8/05 3:33PM  
**Subject:** Fwd: FW: ECD Customer Information Corrective Action

Jim,

Replace the earlier email with this one - David Bennett removed the "PROPRIETARY" notice

Here's is some info I rec'd from David Bennett at Agilent re: the issue of not providing 32.51a info to GL customers. I discussed this with him by phone and he sent this as followup. You and I discussed briefly as well. You and I agreed then, and I still maintain, that this appears to be a self-identified violation of 32.51a with sufficient corrective actions and does not warrant any additional action on our part at this time. The matter should be reviewed during the next inspection.

If you agree, could you have this email and the attachments scanned and filed so the next inspector may review it?

Thanks.  
Bryan

Bryan A. Parker  
Health Physicist  
USNRC Region I - Atlanta Office  
(404) 562-4728  
1-800-577-8510 ext. 24728  
FAX - (404) 562-4955  
bap@nrc.gov

U.S. Nuclear Regulatory Commission  
Region I  
Division of Nuclear Materials Safety  
475 Allendale Road  
King of Prussia, PA 19406-1415

**Mail Envelope Properties** (42092205.B4A : 7 : 34984)

**Subject:** Fwd: FW: ECD Customer Information Corrective Action  
**Creation Date:** 2/8/05 3:33PM  
**From:** Bryan Parker  
**Created By:** BAP@nrc.gov

**Recipients**

nrc.gov  
kp1\_po.KP\_DO  
JPD1 (James Dwyer)

**Post Office**  
kp1\_po.KP\_DO

**Route**  
nrc.gov

| <b>Files</b>    | <b>Size</b> | <b>Date &amp; Time</b> |
|-----------------|-------------|------------------------|
| MESSAGE<br>Mail | 2436        | 02/08/05 03:33PM       |

**Options**

**Expiration Date:** None  
**Priority:** Standard  
**Reply Requested:** No  
**Return Notification:** None

**Concealed Subject:** No  
**Security:** Standard

**From:** <david\_bennett@agilent.com>  
**To:** <bap@nrc.gov>  
**Date:** 2/8/05 3:27PM  
**Subject:** FW: ECD Customer Information Corrective Action

Brian Parker  
Nuclear Regulatory Commission Region I  
Atlanta, GA

Mr. Parker,

Per our conversation of February 3<sup>rd</sup>, I'm following up with further information of the situation where we have not been providing 10 CFR 32.51a required information to customers purchasing our Generally Licensed devices.

Basically, we have identified a problem in our operations where customers have not consistently been sent the information required in 32.51a. We believe this to have occurred over the time frame of September '03 through February '05. We are notifying those customers during said time frame and providing the required information (as demonstrated in the first attachment below).

We have taken the following corrective actions to prevent recurrence:

- Transitioned from paper/multiple document e-mails that were operator dependent for delivery to customers to electronic format that is transmitted to customer as a part of the product quotation (see second attachment)
- Put portion of quotation associated with regulations into controlled format with revision date and document owner for controlling future revisions (3<sup>rd</sup> - 6<sup>th</sup> pages of second attachment)
- Upgraded appropriate procedures reflecting a requirement to monitor the revision date found at the bottom of the fourth page of the quotation (our General License Registration Form). The form is a tracking device we've used for many years that must be completed by the customer and returned to us before processing the order.
- Upgraded the periodic radiation safety program audit performed by this office by requiring the request of a dummy quote from the Order Fulfillment group for any of the products affected by the reg.

In respond to your question as to our receiving permission to send a web site with instructions of applicable NRC regs as opposed to paper or multiple pages of documents, we received such permission from Region I in a letter dated July 12, 2004.

Thanks for your consideration in this case and please contact me by e-mail or phone at 302-633-8262 for further information.

Regards,

David

RSO

Attached are 1) the letter we are sending to our customers and 2) a dummy quote representing one of our part numbered items.

# Σ2

2850 Centerville Road  
Wilmington, DE 19808

February 1, 2005

Ref: ECD Regulatory requirements

Dear ECD Customer,

In order to satisfy U.S. Nuclear Regulatory Commission (NRC) requirements for purchasing general license devices, you are to be provided a copy of certain regulations directing the use and management of such devices. Enclosed is information we are required to provide regarding your ECD and the web address for NRC regulations. In the event you have not received the enclosed information before this notification, please take the time to access, read, and file the regulations identified therein as they must be complied with in order for you to continue using your ECD.

Please retain this letter in your records.

You may contact me at 302-633-8262 if you have questions or do not have web access.

Best regards,

David S. Bennett  
Radiation Safety Officer



## CUSTOMER ECD REGULATORY INFORMATION

Mandatory U.S. Nuclear Regulatory Commission regulations controlling general license Electron Capture Detectors (ECDs) are posted at the NRC 10 CFR web site (<http://www.nrc.gov/reading-rm/doc-collections/cfr/>). Regulations that control the use of your ECD are 10 CFR:

- 20.2201 (Reports of theft or loss of licensed material)
- 20.2202 (Notification of incidents)
- 30.51 (Records)
- 31.2 (Terms and conditions)
- 31.5 (Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere)

***PLEASE NOTE! These regulations, and in particular section 31.5, provide critical control and reporting requirements that must be strictly adhered to. Failure to do so can lead to serious regulatory agency actions.***

Contact the Agilent Technologies, Inc. Little Falls Site RSO at 302-633-8262 if you do not have internet access for a hard copy.

The intended End User must certify on the following “General License Registration Form” that he or she will adhere to these regulations before a sales order can be generated. This form is not a license but a tracking tool enabling Agilent Technologies, Inc. to meet its’ reporting requirements. General Licensees residing in an Agreement State must understand that their ECDs are regulated by their state radiation agency. If you reside in an Agreement State, please contact your state radiation agency to determine any differences between state and federal requirements. Agreement State addresses and phone numbers are listed in the enclosed Appendix D of Section 20.2201.

The following services for ECDs can only be provided by a Specific Licensee:

- Accessing the radioactive source.
- Refurbishing the ECD.
- Transferring ECDs to other General Licensees, except as stipulated in Section 31.5 (c) (9) (enclosed)
- Exporting ECDs, except as stipulated in Section 31.5 (c) (7)

Furthermore, ECDs may only be disposed of through an authorized Licensee. ECDs must be removed from other instruments and disposed of separately. It is not necessary to utilize Agilent Technologies, Inc. for your ECD disposal but the service you do choose must have the specific authorization to handle devices containing Nickel 63. The cost of disposal through Agilent Technologies, Inc. is \$250.00 as of 1/26/01 but will change as necessary. **Warning: NRC’s policy is to issue high civil penalties for improper disposal**

Other important safety information will be provided or referenced in the operator’s manual entitled “Information For General Licensees” which will be shipped with the ECD.



Mr.  
 David L Flad  
 Agilent Technologies, Inc  
 7 Karnik Ct  
 LINCOLN UNIVERSITY PA 19352

## Quotation

TEL: 610-255-4677 FAX: 610-255-5340

| Quote No.                                     | Create Date | Delivery Time | Page       |
|---|-------------|---------------|------------|
| 405689  | 02/08/2005  | 3 Weeks       | 1 of 2     |
| Contact                                       |             | Phone no.     | Valid to   |
| Jay Levine                                    |             | 302-633-7332  | 04/09/2005 |
| <b>To place an order: Call 1-800-227-9770</b> |             |               |            |

| Product/Description   | Qty/Unit | Unit List Price   | Discount Amount | Extended Net Price    |
|---|----------|-------------------|-----------------|-----------------------|
| <b>G1530N</b><br>6890N Network GC System<br>Includes LAN and RS-232 interfaces,7683 interface, detector EPC board, 6-ramp oven programming, 6 heated zones plus oven, keyboard display, 2 analog out.   | 1.000 EA | 10,755.00 USD     |                 | 10,755.00             |
| With the following configuration:<br>Ship-to Country : USA<br>Micro Electron Capture Detector with EPC  |          | 5,672.00 USD      |                 | 5,672.00              |
|   |          | <b>Item Total</b> |                 | <b>16,427.00</b>      |
| <p>A General License Registration Card for certification has been included with this quotation. In order to comply with the NRC state agency U.S. Customers and Puerto Rico must have this certification on file before the electron capture detector (ECD) will be sold or shipped. Prior to order entry this card must be forwarded with your purchase order. Please complete the information and the end user's name, title and telephone who will be responsible for the ECD. To expedite matters, fax this card to 302-633-8953.</p> |          |                   |                 |                       |
|   |          |                   | <b>Total</b>    | <b>: \$ 16,427.00</b> |



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| Contact                                | Phone no.    | Valid to      |        |
| Jay Levine                             | 302-633-7332 | 04/09/2005    |        |
| To place an order: Call 1-800-227-9770 |              |               |        |

### TO PLACE AN ORDER, Agilent offers several options:

- 1) Visit <http://www.agilent.com/chem/supplies> to place online orders using a purchase order or credit card.
- 2) Call 1-800-227-9770 (option 1 then 1) any weekday between 8am and 8 pm Eastern time in the U.S., Canada & Puerto Rico.
- 3) To place an order for Consumables, please fax the order to 302-633-8901.  
To place an instrument and/or software order, please fax the order to 302-633-8953.
- 4) Or you can mail your order to:  
Agilent Technologies  
North American Customer Contact Center  
2850 Centerville Road BU3-2  
Wilmington, DE 19808-1610

### To place an order, the following information is required:

- Your company's purchase order number or
- Your VISA, MasterCard or American Express card and expiration date for credit card orders.

EXCLUSIVE OFFERS FOR NEW INSTRUMENT CUSTOMERS, go to [www.agilent.com/chem/exclusiveoffers](http://www.agilent.com/chem/exclusiveoffers)

### TO CHECK THE STATUS OF AN ORDER:

- 1) Visit [www.agilent.com/chem/supplies](http://www.agilent.com/chem/supplies) to check the status of your order.
- 2) Call 1-800-227-9770 (option 1 then 2 then 2) any weekday between 8 am and 8 pm Eastern time, in the U.S., Canada & Puerto Rico. You will need to know the purchase order or credit card number the order was placed on.

### TERMS AND CONDITIONS:

This offer is subject to Agilent Technologies' Standard Terms and Conditions for Sales and Services,

- Pricing: Web prices are provided only for the U.S. in U.S.dollars. All phone prices are in local currency and for end use. Applicable local taxes are applied.
- All Sales Tax is subject to change at the time of order.
- Shipping and Handling Charges: Orders with a value less than \$2000 or those requiring special services such as overnight delivery may be subject to additional shipping & handling fees. Some of these charges may be avoided by ordering via the Web
- Payment Terms: Net 30 days from invoice date, subject to credit approval.

\* Quotation Validity: This quotation is valid for 60 days unless otherwise indicated.

\* Warranty period for instrumentation is 1 year. The Warranty period for columns and consumables is 90 days.

Visit [www.agilent.com/chem](http://www.agilent.com/chem)

- For Training course information and registration including e-Seminars, select **Education**.
- For Literature, Application notes, and other information, select **Library**.
- For Online Technical Support including the Technical Support Assistant and Frequently Asked Questions, select **Technical Support**.

This Quotation is valid only for the period indicated. All Products and Services quoted are subject to the then-current version of the Agilent Terms and Conditions of Sales and Service (E16), and the then-current versions of any applicable LSCA Supplemental Terms exhibits. A copy of the relevant Agilent Terms & Conditions and Supplemental Terms are either attached or have been previously provided to you. Please contact us if you have not received a copy or require an additional copy. If you have previously signed Agreement with Agilent covering such Products and Services, the terms of that Agreement will take precedence for those Products and Services. Agilent expressly objects to any different or additional terms in your purchase/sales order documentation, unless agreed to in writing by Agilent. Product and Service availability dates are estimated at the time of the quotation. Actual delivery dates or delivery windows will be specified at the time Agilent acknowledges and accepts your purchase order. The above conditions shall apply to the fullest extent permitted by the law governing this transaction and shall not derogate from any statutory or legal rights you may have thereunder. Commodities, technology or software exported from the United States of America (U.S.), or, from other exporting countries will be subject to the U.S. Export Administration Regulations and all exporting countries, export laws and regulations. Diversion contrary to U.S. law and the applicable export laws and regulations is prohibited.



# CUSTOMER ECD REGULATORY INFORMATION

Mandatory U.S. Nuclear Regulatory Commission regulations controlling general license Electron Capture Detectors (ECDs) are posted at the NRC 10 CFR web site (<http://www.nrc.gov/reading-rm/doc-collections/cfr/>). Regulations that control the use of your ECD are 10 CFR:

- 20.2201 Reports of theft or loss of licensed material
- 20.2202 Notification of incidents
- 30.51 Records
- 31.2 Terms and conditions
- 31.5 Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere

***. PLEASE NOTE! These regulations, and in particular section 31.5, provide critical control and reporting requirements that must be strictly adhered to. Failure to do so can lead to serious regulatory agency actions***

Contact the Agilent Technologies, Inc. Little Falls Site RSO at 302-633-8262 if you do not have internet access for a hard copy.

The intended End User must certify on the following "General License Registration Form" that he or she will adhere to these regulations before a sales order can be generated. This form is not a license but a tracking tool enabling Agilent Technologies, Inc. to meet its' reporting requirements.

General Licensees residing in an Agreement State must understand that their ECDs are regulated by their state radiation agency. If you reside in an Agreement State, please contact your state radiation agency to determine any differences between state and federal requirements. Agreement State addresses and phone numbers are listed in the enclosed Appendix D of Section 20.2201.

The following services for ECDs can only be provided by a Specific Licensee:

- Accessing the radioactive source.
- Refurbishing the ECD.
- Transferring ECDs to other General Licensees, except as stipulated in Section 31.5 (c) (9) (enclosed)
- Exporting ECDs, except as stipulated in Section 31.5 (c) (7)

Furthermore, ECDs may only be disposed of through an authorized Licensee. ECDs must be removed from other instruments and disposed of separately. It is not necessary to utilize Agilent Technologies, Inc. for your ECD disposal but the service you do choose must have the specific authorization to handle devices containing Nickel 63. The cost of disposal through Agilent Technologies, Inc. is \$250.00 (reference product number R1629A) as of 1/26/01 but will change as necessary. **Warning: NRC's policy is to issue high civil penalties for improper disposal**

Other important safety information will be provided or referenced in the operator's manual entitled "Information For General Licensees" which will be shipped with the ECD.

# GENERAL LICENSE REGISTRATION FORM

Note: For U.S. customers, Agilent Technologies, Inc. must have this certification on file before the Electron Capture Detector (ECD) will be sold or shipped. Please read the information below, complete the requested information, and sign where indicated. *Please note that the person designated as the End User must be the person identified by the General Licensee as having responsibility for having knowledge of the appropriate regulations and requirements and having the authority for taking required actions to comply with appropriate regulations and requirements as defined in NRC Regulations 10 CFR Section 31.5 (c) (12) (enclosed).*

**The undersigned End User hereby certifies that he/she will adhere to the regulatory requirements in the enclosed NRC Regulations 10 CFR 20.2201, 20.2202, 30.51, 31.2, and 31.5. The undersigned also accepts responsibility for the operation and maintenance of the ECD in a safe manner lying beyond the manufacturer's control.**

ECD Purchased:

6890 Micro - ECD

\_\_\_\_\_ Part numbers G2397A, G2397-60510, G1530N Option 231, or G1540N Option 231

6890 Standard ECD

\_\_\_\_\_ Part numbers G1533-60576, G1533-60660

5890 Series II and Series II Plus ECD

\_\_\_\_\_ Part number G1223A

6850 Series II Micro-ECD

\_\_\_\_\_ Part numbers G2397AB, G2630B Option 231

**Please type or print legibly. Your order may be delayed if information is not legible.**

Customer Purchase Order Number: \_\_\_\_\_

End User's Name: (Print) \_\_\_\_\_ (Signature) \_\_\_\_\_

End User's Title: \_\_\_\_\_ Telephone Number: \_\_\_\_\_

Company Name (No abbreviations please): \_\_\_\_\_

Address (No P.O. Boxes): \_\_\_\_\_ Date: \_\_\_\_\_

**Agilent Only:** Sales Order Number: \_\_\_\_\_

**FAX this page only, once completed, to 302-633-8953**

# Answers to Frequently Asked Questions About General License ECDs

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## ***What is a General License?***

Unfortunately, there is much confusion over the term "General License" because no "license" or document is issued to the recipient of the General License (GL) device. The NRC grants permission to purchase certain low hazard radioactive products without the need to go through an expensive and time-consuming licensure process. The recipient of the device is granted "general license" (more accurately, general permission) to acquire, receive, possess, use, or transfer the device (all described on the first page of 10 CFR 31.5). It's a great benefit in the U.S. but the recipient of the GL device must comply with the regulations noted on the first page of the document entitled Customer ECD Regulatory Information provided by Agilent at the time of the sale. Agilent has U.S. Nuclear Regulatory Commission materials licenses to manufacture and distribute these General License devices, but these licenses do not cover our customers.

## ***Does the customer buy an ECD under Agilent's General License?***

No. As stated above, Agilent has a material license authorizing the company to distribute General Licensed devices to those customers covered under 10 CFR 331.5 (found at the NRC website: <http://www.nrc.gov/reading-rm/doc-collections/cfr/part031/part031-0005.html>). The customer is granted General License to acquire receive, possess, use or transfer the device in accordance with provisions of 10 CFR 31.5.

## ***Can a customer with a Specific License manage General License ECDs under their Specific License?***

Yes. However, the customer must manage their General License ECDs in accordance with the NRC or Agreement State agency's General License regulations and their Specific License ECDs in accordance with the terms of their Specific License

## ***Should a customer purchase a General License ECD and include it under their Specific License?***

This is not recommended. Again, if the customer has a Specific License, they will have to maintain the General License separately (under the NRC or Agreement State General License regulations) from the Specific License requirements.

## ***What if the customer has identified a General License model number in the scope of their Specific License?***

A customer should not list General License model numbers in a Specific License as the ECD would have to be handled under the terms of both the customer's Specific License and the NRC or Agreement State General License regulations. The customer is strongly encouraged to contact the Specific License issuing authority for direction in points of conflict between the terms of the Specific License and General License regulations (e.g., restriction of movement on General License devices vs. Specific Licenses allowing for movement within the scope of the license). It is recommended that the customer consider amending their Specific License to eliminate the General License model from their Specific License.

## ***Why can't we accept a customer's specific (or Materials) license?***

Customers frequently manage General License ECDs under Specific (or Materials) Licenses and will substitute a copy of their license in lieu of completing and returning a copy of the General License Registration Form. We cannot accept these as a substitute for the GLR Form for the following reasons:

- 1) The General Licensee is required to comply with NRC or Agreement State regulations whereas the Specific Licensee is required to comply with the statements and requirements posted on their license. The differences between regulation and license requirements may differ significantly depending on the situation of the Specific Licensee.
- 2) The NRC requires us to provide them with the actual location (by address) of the device. Specific licensees can move their ECDs anywhere within the scope of their license, which in say a university

setting, could be any of dozens of buildings.

3) The General License regulations require the assigning of an individual who will have direct control over the movement of each ECD. The specific licensee identifies a designated RSO, who, in many instances is part of a large institution and not the person with direct day to day control over the device such as a lab manager.

***Can we accept a General License Registration Form in lieu of a customer's Specific License when they order a Specific License ECD?***

No. This is so because:

1) The NRC mandates that we sell our ECDs only to "licensed" customers, and we cannot verify such without a copy of the customer's license.

2) In order to verify that the customer is licensed, we must examine license expiration dates, maximum amounts of Ni-63 allowed under the license, and that the ECD is being shipped to a location within the scope of the customer's license. We simply can't verify these from the information provided in the General License Registration Form.

***What if the customer claims exemption from General License Registration?***

Refer to the ECD procedure GCECD068 maintained in Order Processing, Field Repair, and ECD Lab notebooks.

Basically:

1) Assure the customer that we are not requiring them to file for a license and that the General License Registration Form is only a tracking device for our customer.

2) Inform the customer that we are required to provide the following information to the Nuclear Regulatory Commission and Agreement States for the transfer of the device to their location:

- End User's name\*, title, and telephone number
- Exact street location that the device will be used

\* The person identified by the General Licensee as having responsibility for having knowledge of the appropriate regulations and requirements and having the authority for taking required actions to comply with appropriate regulations and requirements as defined in NRC Regulation 10 CFR Section 31.5 (c) (12)

Please call the RSO at 302-633-8262 if there are any further questions.