

<b>NRC FORM 7</b> (02-2016) 10 CFR 110		 <b>U. S. NUCLEAR REGULATORY COMMISSION</b>		<b>APPROVED BY OMB: NO. 3150-0027</b> Estimated burden per response to comply with this mandatory collection request: 2.4 hours. This submittal is reviewed to ensure that the applicable statutory, regulatory, and policy considerations are satisfied. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollections.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0027), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.		<b>EXPIRES: 11/30/2018</b>	
<b>APPLICATION FOR NRC EXPORT OR IMPORT          LICENSE, AMENDMENT, RENEWAL,          OR CONSENT REQUEST(S)</b> <i>(See Instructions on Pages 4 and 5)</i>							
<b>PART A. FOR NRC USE ONLY</b>		<input checked="" type="checkbox"/> <b>PUBLIC</b> <b>OR</b> <input type="checkbox"/> <b>NON-PUBLIC</b>		DATE RECEIVED			
LICENSE NUMBER <div style="font-size: 1.5em; font-weight: bold; text-align: center;">XB1334</div>		DOCKET NUMBER <div style="font-size: 1.5em; font-weight: bold; text-align: center;">11006251</div>		<div style="font-size: 1.5em; font-weight: bold; text-align: center;">FEB 16 2017</div>		ADAMS ACCESSION NUMBER	
<b>PART B. TO BE COMPLETED FOR ALL LICENSES, AMENDMENTS, RENEWALS, OR CONSENT REQUESTS</b> (If more space is needed to complete any of the items, use Pages 3-4 first, and then attach additional sheets, if necessary.)							
1. NAME AND ADDRESS OF APPLICANT/LICENSEE  Siemens Corporation for Siemens Medical Solutions USA, Inc. 3850 Quadrangle Boulevard Orlando, FL 32817				1a. NAME OF APPLICANT'S CONTACT Neil Trenchard		1b. APPLICANT'S REFERENCE NUMBER NRC3600	
				1c. PHONE NUMBER <div style="text-align: center;">(732) 861-3205</div>		1d. FAX NUMBER	
				1e. E-MAIL ADDRESS neil.trenchard@siemens.com			
2. TYPE OF ACTION REQUESTED <i>(Check One)</i> <div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="width: 20%;"> <input checked="" type="checkbox"/> <b>EXPORT</b> (Parts B, C, E)         </div> <div style="width: 20%;"> <input type="checkbox"/> <b>IMPORT</b> (Parts B, D, E)         </div> <div style="width: 20%;"> <input type="checkbox"/> <b>AMENDMENT/RENEWAL</b> Current License Number:         </div> <div style="width: 20%;"> <input type="checkbox"/> <b>CONSENT REQUEST</b> (Parts B, C) Current License Number:         </div> </div>							
3. CONTRACT NUMBER(S) 4503211336		4. FIRST SHIPMENT DATE 03/01/2017		5. LAST SHIPMENT DATE 02/28/2019		6. PROPOSED EXPIRATION DATE 12/31/2019	
<b>PART C. TO BE COMPLETED FOR EXPORT LICENSES, AMENDMENTS, OR RENEWALS</b> (If more space is needed to complete any of the items, use Pages 3-4 first, and then attach additional sheets, if necessary.)							
7. NAME(S) / ADDRESS(ES) OF SUPPLIERS AND/OR OTHER PARTIES TO THE EXPORT  Siemens Medical Solutions USA Inc. 810 Innovation Drive Knoxville, TN 37932 United States Of America  Please see page number 3 of 3 for additional parties to the export				8. NAME(S) / ADDRESS(ES) OF INTERMEDIATE FOREIGN CONSIGNEE(S)  Siemens Healthcare GmbH Rittigfeld 1 91301 Forchheim Germany  Please see page number 3 of 3 for additional intermediate foreign consignee.		9. NAME(S) / ADDRESS(ES) OF ULTIMATE FOREIGN CONSIGNEE(S)  University of Nahrain-College of Medicine Radiology department, Baghdad - Kademiya Area, Iraq Contact : Dr. Farqad Badr Hamdan phone# +964771055282	
7a. FUNCTION(S) PERFORMED/SERVICE(S) PROVIDED Please see page number 3 of 3				8a. INTERMEDIATE USE(S) Please see page number 3 of 3		9a. ULTIMATE END USE(S) Source for the Biograph 16 Truepoint.	
10. DESCRIPTION OF RADIOACTIVE MATERIALS, SEALED SOURCES, NUCLEAR FACILITIES, EQUIPMENT, OR COMPONENTS; FOR NUCLEAR EQUIPMENT INCLUDE TOTAL DOLLAR VALUE OF EQUIPMENT FOR EXPORT  Germanium -68 Solid Polymer  Four kits. Each kit contains 1 unit of CS-27 and 2 units of LS-LA. Maximum activity per shipment is 185 MBq. Please see page number 3 of 3 .				10a. MAX TOTAL VOLUME / ELEMENT WGT (KG), OR TOTAL ACTIVITY (TBq)  1)CS-27: 11.7 Kg; Max. Activity 92.5 MBq 2)LS-LA Set Up Rod 4.8 Grams Max. Activity 46.25 MBq		10b. MAX ENRICHMENT OR WGT %  CS-27 contains 0.026% Ge-68 LS-LA contains 0.26% Ge-68	
				10c. MAX ISOTOPE WGT (KG)  CS-27 contains 3 grams of Ge-68 LS-LA contains 0.0125 grams of Ge-68 per rod			
11. FOREIGN OBLIGATIONS (BY COUNTRY AND BY PERCENTAGE OF MAXIMUM TOTAL VOLUME) None. 100% US obligated.							

NRC FORM 7  
(02-2016)  
10 CFR 110

U. S. NUCLEAR REGULATORY COMMISSION

**APPLICATION FOR NRC EXPORT OR IMPORT  
LICENSE, AMENDMENT, RENEWAL, OR CONSENT REQUEST(S) (Continued)**


LICENSE NUMBER <b>XB1334</b>	DOCKET NUMBER <b>11006251</b>	ADAMS ACCESSION NUMBER	<input checked="" type="checkbox"/> PUBLIC OR <input type="checkbox"/> NON-PUBLIC
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**PART D. TO BE COMPLETED FOR IMPORT LICENSES, AMENDMENTS, OR RENEWALS**

(If more space is needed to complete any of the items, use Pages 3-4 first, and then attach additional sheets, if necessary.)

12. NAME(S) / ADDRESS(ES) OF FOREIGN SUPPLIERS AND/OR OTHER PARTIES TO IMPORT	13. NAME(S) / ADDRESS(ES) OF INTERMEDIATE CONSIGNEE(S)	14. NAME(S) / ADDRESS(ES) OF ULTIMATE U. S. CONSIGNEE(S)	
12a. NRC EXPORT LICENSE NUMBER(S) (if applicable)	13a. LICENSE NUMBER(S) / EXPIRATION DATE(S)	14a. LICENSE NUMBER(S) / EXPIRATION DATE(S)	
	13b. INTERMEDIATE USE(S)	14b. ULTIMATE END USE(S)	
15. DESCRIPTION OF RADIOACTIVE MATERIALS, SEALED SOURCES, NUCLEAR FACILITIES	15a. MAX TOTAL VOLUME / ELEMENT WGT (KG), OR TOTAL ACTIVITY (TBq)	15b. MAX ENRICHMENT OR WGT %	15c. MAX ISOTOPE WGT (KG)
	16. FOREIGN OBLIGATIONS (BY COUNTRY AND BY PERCENTAGE OF MAXIMUM TOTAL VOLUME)		

**PART E. TO BE COMPLETED FOR ALL LICENSES, AMENDMENTS, RENEWALS OR CONSENT REQUEST(S)**

17. ADDITIONAL INFORMATION PROVIDED ON PAGES 3, 4, AND/OR ON SEPARATE SHEETS? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	17a. COPIES OF RECIPIENTS' AUTHORIZATIONS PROVIDED? <input type="checkbox"/> YES <input type="checkbox"/> NO
18. CERTIFICATION: I, the applicant's authorized official, hereby certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, and that all information provided is correct to the best of my knowledge.	
18a. PRINT NAME AND TITLE OF AUTHORIZED OFFICIAL Neil Trenchard Vice President, Export Control and Customs Siemens Corporation	18b. SIGNATURE -- AUTHORIZED OFFICIAL 
18c. DATE 2-13-17	

NRC FORM 7  
(02-2016)  
10 CFR 110

U. S. NUCLEAR REGULATORY COMMISSION

**APPLICATION FOR NRC EXPORT OR IMPORT  
LICENSE, AMENDMENT, RENEWAL, OR CONSENT REQUEST(S) (Continued)**

LICENSE NUMBER <b>XB1334</b>	DOCKET NUMBER <b>11006261</b>	ADAMS ACCESSION NUMBER	<input checked="" type="checkbox"/> PUBLIC OR <input type="checkbox"/> NON-PUBLIC
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ADDITIONAL INFORMATION (Reference applicable block numbers from page 1 and/or page 2 for each entry)

Item 7) Bollore Logistics USA-Chicago Branch

10700 Waveland Ave

Franklin Park, IL 60131

Bollore Logistics USA is freight forwarder that will ship directly to the intermediate consignee located in Iraq.

Item 8) LAB Consult GmbH

Arasat Street, Hay Babil 929/35/29

Karada, Baghdad, Iraq

Contact Person: Mr. Aqeel Abdulkhaleq Abdulhadi Alwahib, Branch Manager Baghdad, Phone: +964 7706 228 598

Item 8a)

Siemens Healthcare GmbH, Rittigfeld 1, 91301 Forchheim, Germany received an order from the end user. As part of fulfillment to the order, Siemens Healthcare GmbH issued purchase order # 4503211336 to Siemens Medical Solutions (SMS) USA to drop ship items mentioned in block 10 to LAB Consult GmbH. Any subsequent delivery will either be exported to LAB Consult or directly to the end user defined in block 9. After the first delivery of the kit, replacement kits will be delivered to the end user as needed until the expiration of the license.

Item 9 a)

Sealed sources for use in Biograph 16 Truepoint PET/CT medical imaging equipment. Positron emission tomography (PET) is a nuclear medicine, functional imaging technique that is used to observe metabolic processes in the body. The medical system detects cancers, tumors, brain diseases, etc. The system detects pairs of gamma rays emitted indirectly by a positron-emitting radionuclide (or tracer), which is introduced into the body on a biologically active molecule. Three-dimensional images of tracer concentration within the body are then constructed by computer analysis. In modern PET-CT scanners, three dimensional imaging is often accomplished with the aid of a CT X-ray scan performed on the patient during the same session, in the same machine

Product literature attached.

Item 10)

The model CS-27 is the Siemens product name for our 27 cm uniform phantom. A uniform phantom is a cylindrical source that is mechanically sealed with a uniform mixture of solid Ge-68 and polymer inside. The uniform phantom is used to set up the system as well as perform the daily quality control on the scanner. The primary purpose of this scan is to quality control the scanners detectors prior to scanning a patient to ensure everything is operating correctly.

The model LS-LA set up rods are rod (also called line) sources that are used primarily to align the PET scanner with the CT scanner. The rods are made of a solid Ge-68 and polymer mixture that is welded on each end to seal the source. The rods are placed in the scanner field of view and a scan is performed. The PET scanner images the radiation inside the rods and the CT images the physical rod. The two scanners are successfully aligned to create one unit when the two images align.

The PET-CT Phantom includes internal structures which, when imaged with both modalities, can demonstrate how accurately the two image sets are aligned. In addition, a single sample of radioactive water is attenuated by water, bone and CT contrast material (as well as air only) to determine how accurately the CT-based PET attenuation correction works.



February 13, 2017

Deputy Director  
Office of International Programs  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

Re: Export application for Germanium –Ge 68 for medical equipment for end use in Iraq

Dear Deputy Director:

Pursuant to 10 CFR part 110.5, Siemens Corporation on behalf of its wholly-owned subsidiary, Siemens Medical Solutions USA Inc. (SMS), herewith files this license application seeking authorization to export four kits containing Germanium-68 solid polymer sealed sources to Iraq to be used with Siemens medical imaging Biograph Truepoint PET/CT system.

The sealed sources are for use in Biograph 16 Truepoint PET/CT medical imaging equipment. Positron emission tomography (PET) is a nuclear medicine, functional imaging technique that is used to observe metabolic processes in the body. The medical system detects cancers, tumors, brain diseases, etc. The system detects pairs of gamma rays emitted indirectly by a positron-emitting radionuclide (or tracer), which is introduced into the body on a biologically active molecule. Three-dimensional images of tracer concentration within the body are then constructed by computer analysis. In modern PET-CT scanners, three dimensional imaging is often accomplished with the aid of a CT X-ray scan performed on the patient during the same session, in the same machine. The Ge-68 sources kits are primarily used to align the PET scanner with the CT scanner and to quality control the scanner's detectors prior to application on a patient.

Fee of USD 17,400.00 was assigned to this application and has been remitted to the United States Nuclear Regulatory Commission. Please feel free to contact me if I need to furnish additional information.

With best regards,

A handwritten signature in blue ink, appearing to read "Neil Trenchard".

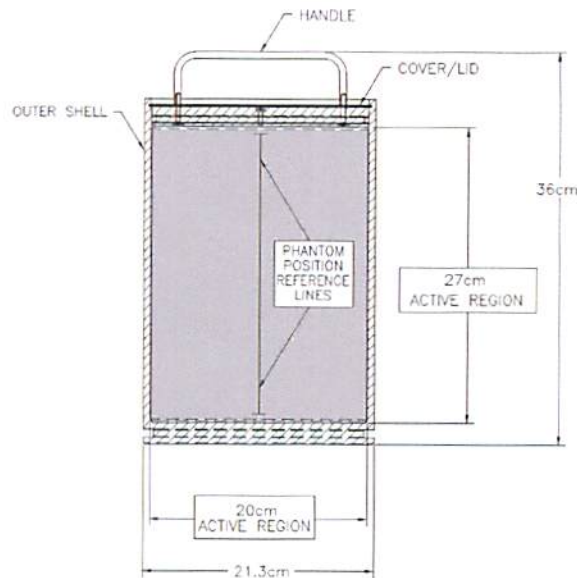
Neil Trenchard  
Vice President, Global Services Export Control and Customs  
Siemens Corporation  
Email: neil.trenchard@siemens.com  
Phone : 732 590 2070

Encl : NRC 7 application form



## CS-27 Phantom Source Product Specifications

The Siemens Uniform CS-27 Phantom is a solid suspension of  $^{68}\text{Ge}$  encased in a cylindrical polyethylene shell. The cylinder is then sealed using a mechanical assembly to create a sealed source. The specific gravity is very close to 1.0.



<u>Model</u>	<u>Minimum Activity</u>	<u>Maximum Activity</u>
CS-27	2.0 mCi (74 MBq)	2.5 mCi (92.5 MBq)

### SPECIFICATIONS

**Activity Accuracy:**  $\pm 5\%$  of measured value, traceable to National Institute of Standards and Technology. The source will ship within the minimum and maximum activity range listed. State of Tennessee source registry TN-237-S-104-S permits the manufacturing and distribution of Model CS Phantoms within the range of less than 10 mCi per source.

**External Contamination:** Guaranteed to be below detectable limits ( $< 0.0005 \text{ mCi/cm}^3$ ).  
Leak test certificate is shipped with each source.

**Approximate Weight:** 11.7 Kilograms

**ISO/ANSI Classification:** ISO/99/C22212(1) / ANSI 97C22212

All sources pass the following test conditions without leakage:

Temp. Range: .....  $-40$  to  $+80^\circ \text{C}$

Pressure Range: .....  $25 \text{ kN/M}^2$  abs. to atmosphere

Impact Test: ..... 50 gram hammer from 1 meter

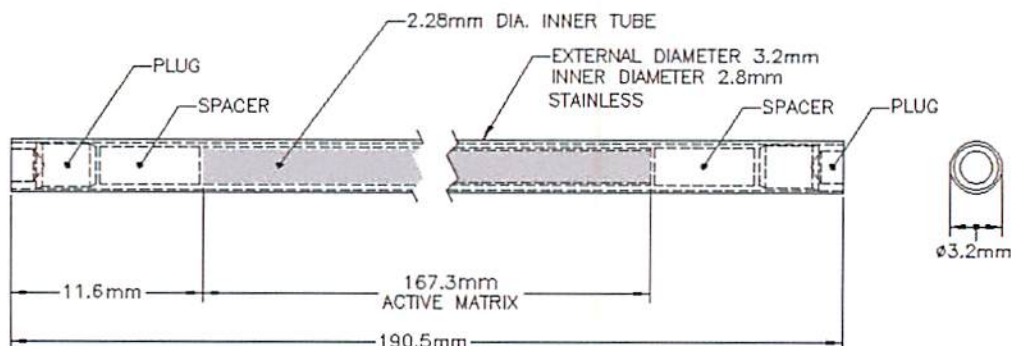
Puncture Test ..... 1 gram pin from 1 meter.

**Uniformity:** Each Phantom is tested to ensure uniformity.

**Shipping/Transport Classification:** Class 7 Radioactive Material, UN2915. Type A Package.

## LS-LA Line Source Product Specifications

The Siemens LS-LA Line Source is a solid suspension of  $^{68}\text{Ge}$  encased in a stainless steel rod welded on both ends to create a sealed source.



<u>Model Number</u>	<u>Minimum Activity</u>	<u>Maximum Activity</u>
LS-LA	1.0 mCi (37 MBq)	1.25 mCi (46.25 MBq)

### SPECIFICATIONS

**Activity Accuracy:**  $\pm 5\%$  of measured value, traceable to National Institute of Standards and Technology. The source will ship within the minimum and maximum activity range listed.

State of Tennessee source registry TN-237-S-103-S permits the manufacturing and distribution of Model LS sources within the range of less than 10 mCi per source.

**External Contamination:** Guaranteed to be below detectable limits ( $<0.0005 \text{ mCi/cm}^3$ ).  
Leak test certificate is shipped with each source.

**ISO/ANSI Classification:** ISO 2919C32312(4) / ANSI 97C32312

**Approximate Weight: 4.8 Grams**

All sources pass the following test conditions without leakage:

Temp. Range: .....  $-40$  to  $+180^\circ \text{C}$   
 Pressure Range: .....  $25\text{-kN/m}^2$  abs. to atmosphere  
 Impact Test: ..... 200-gram hammer from 1 meter  
 Puncture Test: ..... 1-gram pin from 1 meter  
 Bend Test: ..... 3-point & cantilevered bend

**Shipping/Transport Classification:** Class 7 Radioactive Materials, UN2915.

Type A Package.





No:  
Data:

العدد: ٧٧٨ / ح  
التاريخ: ٢٠١٦ / ٤ / ٢٦

إلى/ شركة لاب كونسولت المساهمة الخاصة المحدودة مستشارين للمختبرات العلمية  
والبحثية/ بغداد

م/ ترخيص إستيراد مصادر مشعة داخل العراق

إستناداً للصلاحيات المخولة لنا بموجب القسم السابع من الأمر رقم ٢٢ لعام ٢٠٠٤ ووفقاً لأحكام الفصل السادس/ المادة (٥٣) للنظام الداخلي للهيئة العراقية للسيطرة على المصادر المشعة رقم (١) لسنة ٢٠٠٦ تمنح الهيئة شركتكم المتعاقدة مع شركة كارل كولب الألمانية المتعاقدة مع وزارة التعليم العلمي والبحث العلمي ترخيص لإستيراد مصادر مشعة لصالح جامعة النهرين/ كلية الطب/ قسم الفلسفة والفيزياء الطبية، وتعهدت شركتكم بإعادة تصدير المصادر المشعة إلى الشركة المنتجة عند الإنتهاء من إستخدامها.



رمز الترخيص:	204A-IM-N1
عدد المصادر المشعة:	٣ / ثلاثة
عدد الأجهزة المرافقة:	لا يوجد
إسم المنفذ:	مطار بغداد الدولي
مدة الترخيص:	سنة أشهر من تاريخ الإصدار
الشركة الناقلة:	شركة لاب كونسولت المساهمة الخاصة المحدودة مستشارين للمختبرات العلمية والبحثية
المرفقات:	جدول مصادر مشعة/ صفحة واحدة

محمد إبراهيم عجيل  
رئيس الهيئة  
٢٠١٦/٠٤/٢٦

شروط الترخيص:

- ١- إعلام الهيئة بموعد وصول الشحنة.
- ٢- إعلام الهيئة بموعد نقل الشحنة.
- ٣- المحافظة على مستويات الإشعاع المقررة.

ملاحظة : لا تعفي هذه الوثيقة من الضوابط الخاصة بالإستيراد الصادرة عن وزارة التجارة.

نسخة منه إلى :

- وزارة الدفاع / أمانة السر العام/ للتفضل بالإطلاع ... مع التقدير.
- وزارة المالية/ الهيئة العامة للكمارك/ للتفضل بالإطلاع وإتخاذ مايلزم ... مع التقدير.
- وزارة التعليم العالي والبحث العلمي/ قسم العقود الحكومية، كتابكم ذي العدد/ ع ٧٥٠٩/٩ في ٢٠١٥/١٢/٩، للتفضل بالإطلاع ... مع التقدير.
- وزارة التجارة/ الشركة العامة للمعارض والخدمات التجارية العراقية، للتفضل بالإطلاع وإتخاذ ما يلزم ... مع التقدير.
- جهاز المخابرات الوطني العراقي/ للتفضل بالإطلاع ... مع التقدير.
- مديرية كمرك المنطقة الوسطى/ الإدخال المؤقت، للتفضل بالإطلاع وإتخاذ ما يلزم ... مع التقدير.
- مكتب رئيس الهيئة ... مع التقدير.
- دوائر الهيئة (التراخيص) القسم الطبي والتعليمي/ الخزن، التفتيش، التخطيط والبرامج، الإدارية/ القسم القانوني) لإجراء اللازم ... مع التقدير.
- الصادرة.

204A-IM-N1

جدول بالمصادر المشعة المزمع إستيرادها من قبل شركة لاب كونسولت المساهمة الخاصة المحدودة مستشارين للمختبرات العلمية والبحثية /  
بغداد/ عددها (٣/ ثلاثة)

ت	النظير المشع	الشكل الفيزيائي	النشاط الإشعاعي	تاريخ الميلاد	الرقم التسلسلي	موديل المصدر	الشركة المصنعة	المعايير الدولية IEC, ISO	الإستخدام	العدد
-١	Ge/Ga-68	صلب	mCi	2.5	٢٠١٦/٠٢/٢٤	10961	CS-27	Siemens	-----	٣
-٢	Ge/Ga-68	صلب	mCi	1.25	٢٠١٦/٠٢/٢٤	19476	LS-LA	Siemens	-----	
-٣	Ge/Ga-68	صلب	mCi	1.25	٢٠١٦/٠٢/٢٤	19477	LS-LA	Siemens	-----	





Republic of Iraq  
Council Of Ministers  
Iraqi Radioactive Sources Regulatory  
Authority



جمهورية العراق  
مجلس الوزراء  
الهيئة العراقية للسيطرة على المصادر المشعة

No: K/778  
Data: 26/4/2016

العدد :  
التاريخ :

**To/ Lab Consult GmbH Consultants for Scientific and Research  
Laboratories - Baghdad**  
**Subject/ Authorization Certificate for Importing Radioactive Sources**

According to the article No. (53) of the Regulatory System No.1 in 2006, The Iraqi Radioactive Sources Regulatory Authority (IRSRA) grants authorization to import radioactive sources for **your company** which is contracted with **Karl Kolb Scientific Technical Supplies** which is contracted with **Ministry of Higher Education and Scientific Research** for the benefit of Al-Nahrain University/ Medicine College, the specifications of the sources are in the attached table and your company will be obligated to re-export the sources to the manufacturer when the need for the sources ends up.


License Code:	204A-IM-N1
Radioactive Sources No.:	3/ Three
Accompanied Devices:	None
Border Name:	Baghdad International Airport
License Duration:	Six Months Since Issue Date
Transportation Company	Lab Consult GmbH Consultants for Scientific and Research Laboratories
Attachments:	Radioactive sources table/ one page

**License Conditions:**

- 1-Notifying IRSRA about shipment reach date.
- 2-Notifying IRSRA about shipment transportation date.
- 3-Keeping radiation levels restricted by IRSRA regulations

**Remark:** This certificate by no means exempt from any other regulations and requirements for Import issued by Ministry of Trade.



  
**Mohammed I. Ajeel**  
**Chairman**  
26 April 2016

204A-IM-N1

**Table of Radioactive Sources for Lab Consult GmbH Consultants for Scientific and Research  
Laboratories – Baghdad / Total No. (3/ Three)**

No.	Isotope	Physical State	Activity		Date of Activity	Serial Number	Source Model	Manufacturer	Standards IEC, ISO	Usage	Sum.
1-	Ge/Ga-68	Solid	2.5	mCi	24/2/2016	10961	CS-27	Siemens	-----	Medical Field	3
2-	Ge/Ga-68	Solid	1.25	mCi	24/2/2016	19476	LS-LA	Siemens	-----		
3-	Ge/Ga-68	Solid	1.25	mCi	24/2/2016	19477	LS-LA	Siemens	-----		

