



# HOSPITAL ANDRÉS GRILLASCA, INC.

September 27, 2006

fax: 1(610) 337-5269

Br. 1

Mrs. Pamela Henderson  
Chief Medical Branch Region I Office  
US Nuclear Regulatory Commission  
475 Allendale Road  
King of Prusia, PA 19406-1415

RE: **AMENDMENT REQUEST**  
**LICENSE 52-11832-02**

03034175

Dear Mrs. Henderson:

We are notifying that on September 19, 2006 Dr. José N. Correa removed his HDR machine from our facilities. Nucletron were the responsible for the radioactive source transportation. We are enclosing all the evidence provided for Nucletron of the transportation process.

To compliance with the US Nuclear Regulatory Commission we are requesting an amendment to the license 52-11832-02. Please make the following changes:

- **Delete items-** 6-D (Iridium 192 permitted by 10 CFR 35.600); 7-D (Sealed sources Nucletron Model 105.002); 8-D (2 sources, 1 source not to exceed 13 curies and 1 source not to exceed 8 curies), and 9-D (One source for medical use permitted by 10 CFR 35.600 in a Nucletron Engineering B.V. Model 105.999 remote afterloader unit).
- **Replace the Radiation Safety Officer-**Effective on September 20, 2006, Dr. Miguel A. Serpa was designated as new Radiation Safety Officer of our hospital. Enclosed you will find the Delegation of Authority signed by our Medical Director, Dr. Roberto Velázquez and Dr. Miguel A. Serpa.
- **Remove authorized users-**Dr. José N. Correa from authorized users and Mr. Miguel Ríos from authorized medical physicists.

If you need further information, please call us at (787) 848-0800, extension 2101.

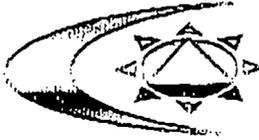
Cordially,

  
Elyonel Pantón Cruz  
Operations Director

jr

Enclosures

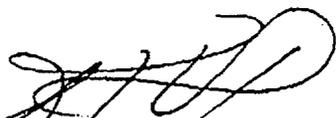
c Mr. Héctor Bermúdez



## HOSPITAL ANDRÉS GRILLASCA, INC.

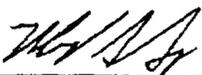
### Delegation of Authority as Radiation Safety Officer

You, Miguel A. Serpa, MD, have been accepted continue in the role as Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation protection program; identifying radiation protection problems, initiating, recommending, or providing corrective actions, verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the Nuclear Regulatory Commission at any time. It is estimated that you will spend 2 hours per week conducting radiation protection activities.

  
\_\_\_\_\_  
Roberto Velázquez, MD  
Medical Director  
Hospital Andrés Grillasca.

09/20/2006  
\_\_\_\_\_  
Date

I accept the above responsibilities,

  
\_\_\_\_\_  
Miguel A. Serpa, MD  
Radiation Safety Officer  
Hospital Andrés Grillasca

09/20/2006  
\_\_\_\_\_  
Date

Correo Yahoo! - hag\_accounting@yahoo.com

Page 1 of 1

**Asunto:** RE: EVIDENCIA TRASLADO FUENTE RADIOACTIVA**Fecha:** Tue, 26 Sep 2006 14:32:21 -0400**De:** "Guevara, Andres" <andres.guevara@us.nucletron.com>  Ver detalles de contacto**Para:** "Elyonel Ponton" <hag\_accounting@yahoo.com>

Dear Johanna

Here is all the documentation that we use when shipping radioactive material. I am also including my service report showing that we removed the source from the unit. If you need something else please let me know.

Thank you

Andres

Andres Guevara  
Field Service Engineer - Central / LATAM  
Nucletron Corporation  
Office: +1 (410) 872 4417  
Mobile: +1 (407) 491 4700  
[andres.guevara@us.nucletron.com](mailto:andres.guevara@us.nucletron.com)  
Visit our website:  
[www.nucletron.com](http://www.nucletron.com)

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**Nucletron**

**Transport Drum (Barrel) Wipe Test Work Sheet  
Sealed Source (Cable) Leak Test Work Sheet**

Nucletron Corporation, Service Department, 8671 Robert Fulton Drive, Columbia, MD 21046 PH. 410-872-4400 Fax 410-312-4196

**INSTRUCTIONS FOR NUCLETRON FIELD SERVICE ENGINEER**

- 1 Follow the USA Nucletron Wipe Test Work Instruction, to perform the tests and analyses described below.
- 2 After the spent source is secured within the shielded inner source shipping container (pig), collect a leak test sample of the sealed source by wiping along the source cable. Using a dry wipe pad, wipe FROM the end of the cable TOWARD the source. Do not touch the wipe to any other surface.
- 3 Collect a wipe test of 300 cm<sup>2</sup> from the exterior of the outer shipping container using a dry wipe. Wipe twice (2x) around the side of the container and twice (2x) across the top using moderate pressure.
- 4 In a low radiation background area, use the "Inspector" Survey Instrument to measure the background count rate and the count rate from each wipe. Place the wipe on the tray, centered under the detector.
- 5 If the BR exceeds 80 cpm, re-measure the background count rate.
- 6 If either wipe exceeds one-half it's limits contact the RSD.
- 7 Measure and record the maximum dose rate on the surface of the outer shipping container and the maximum dose rate at one (1) meter.

Device Serial No. and type	Source Serial No. & Type	Container S/N	Radiation Inst. S/N & Cal	Background BR	LLD = (4.66)(Sqrt B)+3+β	Source Wipe SWR	Drum Wipe DWR
31123	D36A-8119	1023C5	9954	47 cpm	81.95 counts	48 cpm	50 cpm
		Calibrated on	20-Dec-05	If >80 move to lower background area			
		Calibration due	20-Dec-06				
Maximum dose rate (surface):		Maximum dose rate (1 meter)		Current activity:			
0.6 mR/h		0.1 mR/h		0.4 Ci			

**CERTIFICATE OF TRANSPORT DRUM CONTAMINATION ANALYSIS**

The Transport Drum Wipe Test was assayed for beta-gamma contamination. Title 49 CFR 173.443 limits the removable contamination for 300cm<sup>2</sup> surface wipes to less than 120 Bq (0.003 μCi)(6,600 dpm) for external surfaces of packages in transportation.

If DWR is less than or equal to LLD, record "<LLD". Otherwise, Sample Activity = (DWR-BR)/E, where E is the instrument efficiency found on the calibration sticker

Sample Activity < LLD dpm

FSE Signature

Wed Sep 20 06 09/20/06 07:01:18

**CERTIFICATE OF CABLE WIPE TEST**

The Leak Test Sample was assayed for beta-gamma contamination. Title 10 CFR 35.59 limits the removable contamination from a sealed source used in brachytherapy to 200 Bq (0.005 μCi)(11,100 dpm).

If SWR is less than or equal to LLD, record "<LLD". Otherwise, Sample Activity = (SWR-BR)/E, where E is the instrument efficiency found on the calibration sticker

Sample Activity < LLD dpm

FSE Signature

Wed Sep 20 06 09/20/06 07:01:28

Hospital: Hosp Andres Grillasca  
Address: Ruta # 14  
Ponce, Puerto Rico 00733

Note to licensee: This report should be reviewed by your Radiation Safety Officer and filed for future reference.

Contact name: Dr. Correa

# Field Service Report



## Nucletron

Nucletron Corporation, Service Department, 8671 Robert Fulton Drive, Columbia, MD 21046 Phone: 410-872-4400 Fax: 410-312-4195

Customer Hosp Andres Grillasca	<input type="checkbox"/> Phone	<input type="checkbox"/> Recall	<input type="checkbox"/> Repair	Call No.	Rtn Visit Required		
Address Ruta # 14 Ponce, Puerto Rico 00733	<input checked="" type="checkbox"/> Install	<input type="checkbox"/> Training	<input type="checkbox"/> PM	SPC Codes	Equip	Failure	Action
Phone No.	<input type="checkbox"/> CA	<input type="checkbox"/> Other		Serial No.	31123		
PQ No.	<input type="checkbox"/> Contract	<input type="checkbox"/> No Charge	<input checked="" type="checkbox"/> Bill	FW version	1.43		
Dosimeter Reading: 0 mR	<input type="checkbox"/> Install	<input type="checkbox"/> Warranty	<input type="checkbox"/> Other	Date in	19-Sep-06	Out	20-Sep-06
				Time in	16:00	Out	19:00

Symptom  
Remove active source so that unit can be re-located.

Resolution  
Removed source and installed a dummy. Unit will be moved to a new location.

**For Office Use Only - This Is Not An Invoice**

Qty used	Description	Part Number Part From?	Qty ret	Return Status Return Method	RX Call No (if different)	Description of problem / failure

Travel Regular	Hrs	Technical Support Regular	Hrs	Airfare	
Travel Overtime	Hrs	Technical Support Overtime	Hrs	Rental Car	
Travel Saturday	Hrs	Technical Support Saturday	Hrs	Hotel	
Travel Sunday	Hrs	Technical Support Sunday	Hrs	No of Miles	\$0.00
Travel Bank Holiday	Hrs	Technical Support Bank Holiday	Hrs	Travel Expenses (Meals, Tolls, etc)	

We certify that the work carried out in all sections of this document has been carried out in accordance with the manufacturer's instructions by Nucletron's authorized representative with proper supervision by:

Engineer *[Signature]*

Customer

Wed Sep 20 2006 09:04:56

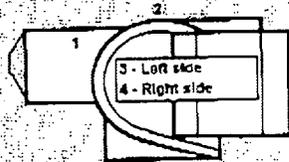


**Nucletron**

**Survey/Source Exchange  
microSelectron-HDR Version 2**

Nucletron Corporation, Service Department, 8671 Robert Fulton Drive, Columbia, MD 21046 PH: 410-872-4400 Fax: 410-312-4196

Serial No. 31123	Physicist/RSO on location: Dr. Correa	Service Engineer: AGA	
Date: September 19, 2006	Hospital: Hosp Andres Grillasca	City, State & Country: Ponce, Puerto Rico 00733	
Survey Instrument Type: LUDLUM	Serial No.: 170193	Personal Dosimeter Type: CANARY III	Serial No.: 572
Calibration Date: January 25, 2006	Recalibration Due: January 25, 2007	Calibration Date: November 22, 2005	Recalibration Due: November 22, 2006



Head Survey		Last 5 Major Error Codes	
1	mR/h @ 10cm	1	
2	mR/h @ 10cm	2	
3	mR/h @ 10cm	3	
4	mR/h @ 10cm	4	
5	mR/h @ 10cm	5	
6	mR/h @ 10cm	Number of source runs	
Old Source	New Source	166	

**Survey Checklist**

**Step 8 - Voltages**

a.  Vdc - Lock  Vdc - Unlock locking ring

b.  Vdc - Connect  Vdc - Disconnect applicator

c.  Vac - Mains voltage

d.  Vdc - +24 VBA (disconnected) (J6:1 - 2)

e.  Vdc - Input voltage PSC (J7:1 - 2)

f.  Vdc - 28VS (J5:1 - 2)

g.  Vdc - +5VP (TP1 - TP2)

h.  Vdc - +5VSP (TP3 - TP4)

i.  Vdc - Across R344/R349

j.  1.00 Ω - Impedance R344/R349

k.  mA - Trickle charge current

**Step 16 - Battery Check Procedure**

a.  Vdc - Monitor VBA during 1min power fail

b.  mA - Peak recharge current Voltage \_\_\_\_\_ Vdc

c.  mA - Recharge current after 7min Voltage \_\_\_\_\_ Vdc

**Yearly Checks/Replacements:**

- Indexer cleaning
- O-Ring replacement - Every 2 years
- Batteries - Every 2 years
- Check that all head mountings are tight
- Telescope up/down times
- Wire-in switches, check and source
- Annual emergency procedures inservice training

1.  Power on TCS. Print out self test for reference

2.  Print system overview & message logbook for reference

3.  Remove source, install dummy

Source No.	D36A-8119	na	Number of check cable runs	
Container No.	1023C5	na	3149	
Activity	Old	0.4	Ci	New
On Date	19-Sep-06			

- 4. Verify radiation detector functionality
- 5. Perform system backup
- 6. Wipe test source cable
- 7. Clean  7a. Replace reference opto pair
- 8. Treatment unit voltage checks - see step 8
- 9. Test treatment via floppy disk. Import from PLATO
- 10. Indexer check channels 1, 5, 10, 15, 18
- 11. Interrupt from TCP
- 12. Check master emergency stop @ TCP
- 13. Check auxiliary emergency stops
- 14. Check TU emergency stop
- 15. Power failure
- 16. Battery check procedure - see step 16
- 17. Restore power
- 18. Verify return, proper status codes
- 19. Restart, verify TCS retained data
- 20. 10 minute timer check
- 21. Door interlock(s) operation
- 22. Install new check cable if applicable
- 23. Restore database
- 24. Transport index - new source, old source
- 25. Install new source
- 26. Exchange isotope labels
- 27. Wipe test transport container
- 28. Complete source return documents

Remarks:

This is to acknowledge the receipt of your letter/application dated

9/27/2006, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment 52-11932-02 There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

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A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 139477.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.