



UNITED STATES  
**NUCLEAR REGULATORY COMMISSION**  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

July 11, 2005

Docket No. 03019882  
Control No. 136357

License No. 52-21175-01

Jorge Perera  
General Manager  
Baxter Healthcare Corporation  
P.O. Box 1389  
State Road 721, Km 0.3  
Aibonito, PR 00705

SUBJECT: BAXTER HEALTHCARE CORPORATION, LICENSE RENEWAL, CONTROL  
NO. 136357

Dear Mr. Perera:

This refers to your request for renewal of your NRC license. Enclosed with this letter is the renewed license. Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

Evidence of financial assurance submitted with your application is currently adequate, however, as discussed in your letter of June 20, 2005, you are in the process of replacing your letter of credit which will expire July 31, 2005. This licensing action is being separately tracked as NRC Control No. 136897. Furthermore, please be advised that the revised requirements for financial assurance as stipulated in 10 CFR 30.35 necessitate that you submit a decommissioning funding plan to the NRC by December 2, 2005.

The NRC expects licensees to conduct their programs with meticulous attention to detail and high standards of safety and compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your program according to NRC regulations, the conditions of your NRC license, and the representations made in your application. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify the NRC in writing of any change in mailing address.
3. In accordance with 10 CFR 30.36(d), notify the NRC, promptly, in writing, and request termination of the license
  - a) when you decide to terminate all activities involving materials authorized under the license; or

- b) if you decide not to acquire or possess and use authorized material.
4. Request and obtain a license amendment before you:
- a) change Radiation Safety Officers;
  - b) order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license; or
  - c) add or change the areas of use, or addresses of use identified in the license application or on the license; or
  - d) change the name or ownership of your organization.
5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations.

You will be periodically inspected by the NRC. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and the representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, imposition of a civil penalty, or an order suspending, modifying or revoking your license.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Current NRC regulations and guidance are available at the NRC web site at <http://www.nrc.gov/materials/miau/mat-toolkits.html> and <http://www.nrc.gov/who-we-are/governing-laws.html> or by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

***Original signed by Judith A. Joustra***

Judith A. Joustra  
Senior Health Physicist  
Materials Security and Industrial Branch  
Division of Nuclear Materials Safety

Enclosure:

J. Perera  
Baxter Healthcare Corporation

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Amendment No. 15

cc:  
Angel M. Alicea, Radiation Safety Officer

**This Document is Sensitive and Should Be Non-Public.**

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**SISP Review Complete: (JWS)**

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OFFICE	DNMS/RI	N	DNMS/RI	N	DNMS/RI			
NAME	JSchmidt /JWS2/		JJoustra /JAJ/					
DATE	7/11/05		7/11/05					

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**MATERIALS LICENSE**

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p style="text-align: center;">Licensee</p> <p>1. Baxter Healthcare Corporation</p> <p>2. P.O.Box 1389 State Road 721, Km 0.3 Aibonito, Puerto Rico 00705</p>	<p>In accordance with the application dated January 25, 2005,</p> <p>3. License number 52-21175-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date July 31, 2015</p> <hr/> <p>5. Docket No. 030-19882 Reference No.</p>
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|---|--|--|
| 6. Byproduct, source, and/or special nuclear material | 7. Chemical and/or physical form                   | 8. Maximum amount that licensee may possess at any one time under this license |
| A. Cobalt 60  | A. Sealed Sources (MDS Nordian Model C-188 Series) | A. 5,000,000 Curies  |

9. Authorized use:
- A. For use in an MDS Nordian Model JS 8900 irradiator for irradiation of material except explosives, flammables or corrosives. These sources are also authorized for use in the MDS Nordian Model JS 3100 Underwater Calibrator used for dosimeter calibration.

**CONDITIONS**

10. Licensed material may be used only at the licensee's facilities located at State Road 721, Km 0.3, Aibonito, Puerto Rico.
11. Licensed material shall be used by, or under the supervision of, individuals who have satisfactorily completed the training and examination described in the application dated January 25, 2005, and letter dated June 20, 2005, and have been designated in writing by the Radiation Safety Officer. The licensee shall maintain records of individuals designated as users for 3 years following the last use of licensed material by the individual.
12. The Radiation Safety Officer for this license is Angel M. Alicea.
13. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
52-21175-01

Docket or Reference Number  
030-19882

Amendment No. 15

14. The licensee shall implement the material accountability program described in the application dated January 25, 2005, and letter dated June 30, 2005, to account for all sealed sources containing licensed material received and possessed under the license.
15. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal, replacement, and disposal of sealed sources in the irradiator shall be performed by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
16. Nothing in this license relieves the licensee from complying with the rules and regulations of the U.S. Food and Drug Administration, or any other requirements governing the irradiation and distribution of foods for human consumption.
17. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
18. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated January 25, 2005 (ML050280439)
  - B. Letter dated June 20, 2005 (ML051740587)
  - C. Letter dated June 30, 2005 (ML051870185)

For the U.S. Nuclear Regulatory Commission

***Original signed by Judith A. Joustra***

Date July 11, 2005

By

Judith A. Joustra  
Materials Security and Industrial Branch  
Division of Nuclear Materials Safety  
Region I  
King of Prussia, Pennsylvania 19406