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**Robert Packer Hospital**  
One Guthrie Square  
Sayre, PA 18840-1698  
Tel 570.888.6666

September 8, 2003

George Pangburn, Director  
Division of Nuclear Materials Safety  
Nuclear Regulatory Commission – Region 1  
475 Allendale Road  
King of Prussia, PA19405-1415

Docket No. 03003013  
CAL No. 1-03-003

37-01893-01

Dear Mr. Pangburn:

I am writing in follow-up to the confirmatory action letter (CAL 1-03-003) issued to Robert Packer Hospital on July 28, 2003 (revision letter on July 30, 2003). Specifically, this letter shall serve as the written report for the independent medical physicist review to confirm the adequacy of the current Robert Packer Hospital prostate seed implant program.

The following is a brief summary of the independent review. On August 23, 2003, the Robert Packer Hospital current prostate seed implant program was reviewed by Brennan MacDonald, Ph.,D.A.B.R. This on-site review included a random sampling of ten prostate seed implant cases performed between the dates of January 1, 2003 to August 23, 2003. The total number of prostate seed implant cases performed during this same time interval was 16, thus the random sampling constituted 62% of all cases performed.

Each case was reviewed for the following: a review of the medical directive and planned seed location, a review of the actual seed location, and a review of the target volume receiving the prescribed dose. Mr. McDonald also evaluated the accuracy of dosimetric calculations produced by the treatment planning software.

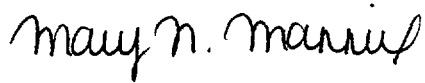
This review confirmed:

- Good correlation between planned seed locations and actual locations, with all cases showing at least 90% of the target volume receiving the prescribed dose.
- Dosimetric calculations produced by the treatment planning software in agreement with currently accepted characteristics of the seed isotope model used by Robert Packer Hospital.

Enclosed you will find both a copy of Mr. Brennan MacDonald's curriculum vitae as well as the written report submitted to Robert Packer Hospital on August 29, 2003.

This letter addresses all components of the independent medical physicist review as requested in point 7 of the confirmatory action letter. Should you have any questions, please do not hesitate to contact me directly at (570) 882-4453.

Sincerely,

A handwritten signature in cursive script that reads "Mary N. Mannix".

Mary N. Mannix, FACHE  
Chief Operating Officer

cc: William F. Vanaskie  
Ralph D. Zehr, MD  
Gary Proulx, MD  
Sandra Gabriel

Enclosures

# Memo

**To:** Mary Mannix, Robert Packer Hospital  
**From:** Brennan MacDonald, Ph.D., D.A.B.R.  
**Date:** 8/29/2003  
**Re:** Review of Robert Packer Hospital Current Prostate Seed Implant Program

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I recently completed a review of the prostate implant program at Robert Packer Hospital on 8/23/03. My findings are listed below.

A random sampling of ten cases performed from 1/1/03 until 8/23/03 has demonstrated good correlation between planned seed locations and actual locations, with all cases showing at least 90% of the target volume receiving the prescribed dose. This, combined with accurate seed strengths and planning, is the cornerstone of a successful program.

I met with the radiation oncologist and physics staff, none of whom were involved in the problem cases performed in the past, and who expressed a sincere desire to perform only the highest quality implants.

I evaluated the accuracy of dosimetric calculations produced by their treatment-planning software with its present configuration and found it to agree with currently accepted characteristics of the seed isotope and model used by Robert Packer Hospital.

Radioactive material receipt and shipment were well documented with adequate security for seeds awaiting use and shipment.

Survey instrumentation was found to be in good working order with up-to-date calibrations.

I recommended:

- That the hospital take those steps necessary to attract and retain a qualified medical physicist in order to provide the continuity of care that is necessary for a successful program.
- That policies and procedures necessary to assure a safe quality management program be reviewed by a qualified medical physicist, and that the physicist report to a Radiation Safety Committee knowledgeable in the applicable regulations as set forth in 10CFR35.
- That these policies should stipulate that seeds be ordered and received by the medical physicist or his designee, and that that designee should have no less training than a medical dosimetrist.
- That a dedicated system e.g. Standard Imaging's HDR Plus well chamber, appropriate for seed calibration be purchased, calibrated for I-125 seeds, and used on a representative

sampling from all seed orders. This will provide greater confidence in the measurements than the nuclear medicine dose calibrator currently in use.

- That the ultrasound probe/stepper combination be evaluated regularly – no less frequently than monthly - for proper agreement between predicted and actual template hole placement.
- That the team continue to perform their implants under both ultrasonic guidance and consider the use of fluoroscopic guidance to verify needle and seed placement.



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Brennan A. MacDonald, Ph.D., D.A.B.R.

# Curriculum Vitae

## Brennan A. Mac Donald, M.Sc., Ph.D., D.A.B.R.

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### PERSONAL INFORMATION

Home address:

[REDACTED]

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Tel. [REDACTED]

Date of birth:  
Place of birth:  
Citizenship:

[REDACTED]

S S N:  
Civil Status:  
Languages:

[REDACTED]  
English, French

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### EDUCATION

1985	Undergraduate:	Dip. Engr.:	Honours. St. Francis Xavier University, Antigonish, Nova Scotia
1988	Undergraduate:	B.Sc. (Physics):	Honours. St. Francis Xavier University, Antigonish, Nova Scotia
1991	Graduate:	M.Sc. (Medical Physics):	<i>Surface charge characteristics of a radio-charged electret dosimeter</i> McGill University, Montreal, Quebec.
1994	Graduate:	Ph.D. (Medical Physics):	<i>Charge transport and storage in the radio-charged electret dosimeter.</i> Dean's Honour List McGill University, Montreal, Quebec

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### Certifications and Licenses

1996	Radioactive Material License, Florida, # 64-12
1996	Radioactive Material License, Florida, # 2223-1
1998	Radioactive Material License, NRC, #24 01143 06
1998	American Board of Radiology, Diplomate in Radiotherapy Physics
1998	Florida Department of Health, Therapeutic Radiological Physicist, License Number TRP-0000127

**PERSONAL INFORMATION WAS REMOVED  
BY NRC. NO COPY OF THIS INFORMATION  
WAS RETAINED BY THE NRC.**

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## SPECIAL TRAINING

1996	<i>Clinical High Dose-Rate Brachytherapy Treatment Planning with Plato BPS.</i> Nucletron Corporation, Columbia, MD
1997	<i>Radiation Safety Officer's Course</i> University of Texas, San Antonio, San Antonio, Texas
1998	<i>Permanent, Transperineal, Ultra-sound Guided Brachytherapy in the Management of Localized Prostate Cancer.</i> University of Washington Medical Center, Seattle, WA
1999	<i>Pinnacle3: Three Dimensional External Beam Treatment Planning.</i> ADAC Laboratories, San Jose, CA

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## AWARDS

1988-1992	<b>National Science &amp; Engineering Research Council (Canada)</b> Graduate Studies Scholarships
1991	<b>McGill University</b> Major Fellowship (unaccepted)
1985	<b>St. Francis Xavier U.</b> Gold Medal, engineering program
1983-1987	<b>St. Francis Xavier U.</b> Alumni Scholarship

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## EMPLOYMENT

### Summary of Experience:

•	<b>Supervision</b>	Four years of managerial experience including one multi-center department comprising three physicists (including myself), three dosimetrists and one engineer and one .
•	<b>Calibration</b>	TG-21 Protocol, All brachytherapy sources
•	<b>Radiation</b>	RSO
•	<b>Safety</b>	
•	<b>QA</b>	Linear accelerators, Co-60 teletherapy units and HDR brachytherapy units (Nucletron $\mu$ -selectron, and Selectron), 2d treatment-planning (Target, Theraplan, ROCS), 3d treatment planning (CadPlan, ADAC Pinnacle, Prowess 3D)
•	<b>Techniques</b>	Total Body Irradiation (Photons) Half Body Irradiation Single Isocenter, Rotating Half-block Breast Technique Electron Arc, HDR brachytherapy treatment of <b>prostate, breast, bronchus, oesophagus, rectum, Gyn, skin lesions and interstitial implants</b> <b>LDR permanent prostate implants</b> (conventional and CT-guided), Gyn treatment, Strontium eye treatment
•	<b>Commissioning</b>	Varian Clinac 2300C/D, 2100C/D, Clinac 1800, Clinac 6/100. Dynamic wedge and multi-leaf collimator
•	<b>etc</b>	Attenuator design, Unix system administration, C++ for Mac, Fortran, Visual Basic for Windows programming, Teaching Residents, Technology students and MSc-level physicists. Development of HDR program .

**Montreal General Hospital, McGill University, Montréal, Québec.**

Apr. 1994 - Mar 1996 Medical Radiation Physicist - Department of Medical Physics. Shared responsibility for: QA of 5 linear accelerators, 2 Cobalt-60 Units, high-dose-rate after-loading brachytherapy units (Selectron and Microselectron), GE Target and Cad Plan treatment planning computers. Planning and administration of HDR brachytherapy treatments. Lecturer.

**Mt. Sinai Comprehensive Cancer Center, Miami Beach, Florida.**

Mar. 1996 - Jul. 1997 Chief of Medical Physics - Department of Radiation Oncology. Supervision of one other physicist, one engineer and three dosimetrists. Responsibility for: calibration and QA of 3 linear accelerators, 2 Cobalt-60 Units, 1 high-dose-rate after-loading brachytherapy unit (Microselectron), Theraplan treatment planning system and LDR brachytherapy program (Cs-137, Ir-192 and US Guided Permanent Prostate implants of I-125, Pd-103 and Au-198). Planning and administration of HDR brachytherapy treatments. Member of Radiation Safety Committee.

- Successfully oversaw the development of HDR programme.
- Converted treatment procedure for chest-walls and breasts from SSD to SAD technique.
- Obtained license for radioactive materials for satellite clinic from State of Florida (2223-1), and am the named teletherapy physicist on two such licenses (Florida 2223-1 and 64-12)

**Lester E. Cox Medical Center, Springfield, Missouri.**

Jul. 1997 - Jul. 1998 Medical Physicist - Department of Radiation Oncology. Sole physicist in a department treating sixty patients per day. Supervised two dosimetrists and five therapists. Responsibility for: calibration and QA of 2 linear accelerators, 1 high-dose-rate after-loading brachytherapy unit (Microselectron), ADAC and Rocs treatment planning systems and LDR brachytherapy program (Cs-137). Planning and administration of HDR brachytherapy treatments. Radiation Safety Officer and Member of Radiation Safety Committee. (NRC License #24 01143 06)

**Mt. Sinai Comprehensive Cancer Center, Miami Beach, Florida.**

Jul. 1998 - Jan. 2000 Regional Director, Medical Physics - Department of Radiation Oncology. Supervision of two other physicists, one engineer and three dosimetrists. Responsibility for: calibration and QA of 3 linear accelerators, 2 Cobalt-60 Units, 1 high-dose-rate after-loading brachytherapy unit (Microselectron), Theraplan treatment planning system and LDR brachytherapy program (Cs-137, Ir-192 and US Guided Permanent Prostate implants of I-125, Pd-103 and Au-198). Planning and administration of HDR brachytherapy treatments. Member of Radiation Safety Committee.

**Radiation Physics, Inc., Miami, Florida.**

Jan. 2000 - Mar. 2002 Medical Physicist - Sharing responsibility for coverage of several radiation oncology clinics. Overseeing prostate implant planning.

**Elliot Hospital, Manchester, New Hampshire.**

Jan. 2000 - Mar. 2002 Director, Medical Physics - Director of regional department. Three physicists, five dosimetrists, four linear accelerators.

## ADDITIONAL ACTIVITIES

- Performing QA and Radiation Safety analyses for dental and chiropractic offices equipped with diagnostic X-ray tubes.
- Authoring numerous Windows-based, RT-related software packages, one of which - a 3D package for pre and post-planning prostate implants - received FDA 510(k) clearance, and all of which are used clinically.

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## RESEARCH

### Publications in peer-reviewed journals

1. B.G. Fallone and B.A. Mac Donald, *Surface charge distributions during the charging and discharging of electrets produced in electret ionization chambers*, IEEE Trans Elect Insul, **27**, pp. 144-151, 1992.
2. B.A. Mac Donald, B.G. Fallone and L.N. Ryner, *Feasibility study of an electret dosimetry technique*, Phys. Med. Biol., **37**, pp. 1825-1836, 1992.
3. B.G. Fallone, B.A. Mac Donald and L.N. Ryner, *Characteristics of a radiation-charged electret dosimeter*, IEEE Trans. Elect. Insul., **28**, pp. 143-148, 1993.
4. B.G. Fallone and B.A. Mac Donald, *Modeling of surface charge distributions in electret ionization chambers*, Rev. Sci. Instrum., **64**, pp. 1627-1632, 1993.
5. J. Sergent, S. Ohta and B.A. Mac Donald, *Functional neuroanatomy of face and object processing, a positron emission tomography study*, Brain, **115**, pp. 15-36, 1992.
6. J. Sergent, S. Terriah, E. Zuck and B.A. Mac Donald, *Distributed neural networks underlying musical sight reading and keyboard performance*, Science, **257**, pp. 106-109, 1992.
7. J. Sergent, E. Zuck, M. Levesque and B.A. Mac Donald, *Positron emission tomography study of letter and object processing: empirical findings and methodological considerations*, Cereb. Cortex, **2**, pp. 68-70, 1992.
8. B.A. Mac Donald, B.G. Fallone and A. Markovic, *Radiation-induced conductivity of Teflon in electret ionization chambers*, J. Physics D: Applied Physics, **26**, pp. 2015-2021, 1993.
9. B.A. Mac Donald and B.G. Fallone, *Charge decay of electrets formed by ionizing radiation in air*, J. of Electrostatics, **31**, pp. 27-33, 1993.
10. B.A. Mac Donald and B.G. Fallone, *Improved modeling of surface charge distributions in electret ionization chambers*, Rev. Sci. Instrum., **65**, pp. 730-735, 1994.
11. M. Gosselin, M.D.C. Evans, B.A. Mac Donald, M. Olivares-Pla and E.B. Podgorsak, *Equivalent square as a predictor of depth of dose maximum for megavoltage therapy machines*, Med. Dosimetry, **21**, pp. 145-148, 1996.
12. D. Donath, T. Vuong, G. Shenouda, B. Mac Donald and R. Tabah, *The potential uses of HDR brachytherapy in patients with head and neck cancer*, European Archives of Otorhinolaryngology, **252**, pp. 321-324, 1999.

### Book Chapters and Conference Proceedings

1. B.A. Mac Donald and B.G. Fallone, *Surface charge distributions on radiation charged electrets*, Proceedings of the 7th International Symposium on Electrets, IEEE Dielectric and Electrical Insulation Societies, Editors R. Gerhard-Melthaupt, W. Kunstler, L. Brehmer and R. Dantz, Berlin Germany, pp. 765-770, 1991.
2. B.G. Fallone, B.A. Mac Donald and L.N. Ryner, *Characteristics of a radiation charged electret dosimeter*, Proceedings of the 7th International Symposium on Electrets, IEEE Dielectric and Electrical Insulation Societies, Editors R. Gerhard-Melthaupt, W. Kunstler, L. Brehmer and R. Dantz, Berlin Germany, pp. 798-804, 1991.
3. J. Sergent, B.A. Mac Donald and E. Zuck, *Structural and functional organization of knowledge about faces and proper names: a PET study*, Attention and Performance XV, Eds. C. Umiltà and M. Moscovitch, Lawrence Erlbaum and Associates, Hillsdale, N.J., pp. 632-640, 1991.



4. M.D.C. Evans, E.B. Podgorsak, M. Pla, L.J. Schreiner, B.G. Clark, B.A. Mac Donald and C. Pla, *Dosimetric characteristics of surface applicators for high dose-rate brachytherapy*, Proceedings of the Annual Meeting of the Canadian College of Physicists in Medicine and the Canadian Organization of Medical Physicists, June 4-7, 1995, Montreal, QC
5. M. Gosselin, M.D.C. Evans, B.A. Mac Donald, M. Pla and E.B. Podgorsak, *Equivalent square as a predictor of depth of dose maximum for megavoltage therapy beams*, Proceedings of the Annual Meeting of the Canadian College of Physicists in Medicine and the Canadian Organization of Medical Physicists, June 4-7, 1995, Montreal, QC

## Published Abstracts

1. L. Ryner, B.G. Fallone and B.A. Mac Donald, *Development of a novel electret dosimeter*, Radiology, 173 Supplement, 431, 1989.
2. L. Ryner, B.G. Fallone and B.A. Mac Donald, *The Development of an electret dosimeter*, Medical Physics, 17(3), 535, 1990.
3. B.A. Mac Donald, B.G. Fallone and L. Ryner, *Charge distribution and stability on the radio-charged electret*, Medical Physics, 17(4), 743, 1990.
4. B.A. Mac Donald, B.G. Fallone and L. Ryner, *Surface charge distributions in radiation charged electrets*, Medical Physics, 18(3), 601, 1991.
5. B.A. Mac Donald and B.G. Fallone, *Surface charge distributions on radiation-charged electrets*, 7th International Symposium, Abstract Publication p. 62, IEEE Dielectric and Electrical Insulation Society

## Presentations to Research Conferences

(\* denotes presenting author)

1. L. Ryner\*, B.G. Fallone and B.A. Mac Donald, *Development of a novel electret dosimeter*, 75th Annual Assembly of the Radiological Society of North America & American Association of Physicists in Medicine, Nov. 26 - Dec. 1, 1989, Chicago, Ill.
2. B.A. Mac Donald\*, B.G. Fallone and L.N. Ryner, *Surface charge characteristics of a radiation charged electret*, Annual Meeting of the Canadian College of Physicists in Medicine and the Canadian Organization of Medical Physicists, June 6-9, 1990, Montreal, QC.
3. L. Ryner\*, B.G. Fallone and B.A. Mac Donald, *An electret dosimeter for personnel monitoring*, Annual Meeting of the Canadian College of Physicists in Medicine and the Canadian Organization of Medical Physicists, June 6-9, 1990, Montreal, QC.
4. B.A. Mac Donald\*, B.G. Fallone and L.N. Ryner, *Charge distribution and stability on the radio-charged electret*, American Association of Physicists in Medicine 32 Annual Meeting and Technical Exhibition, July 22-26, 1990, St. Louis, MI.
5. L. Ryner\*, B.G. Fallone and B.A. Mac Donald, *The development of an electret dosimeter*, American Association of Physicists in Medicine 32 Annual Meeting and Technical Exhibition, July 22-26, 1990, St. Louis, MI.
6. B.A. Mac Donald\* and B.G. Fallone, *Surface charged distributions in radiation charged electrets*, American Association of Physicists in Medicine 33 Annual Meeting and Technical Exhibition, July 20-26, 1991, San Francisco, CA
7. B.G. Fallone\*, B.A. Mac Donald and L.N. Ryner, *Characteristics of a radiation charged electret dosimeter*, Proceedings of the 7th International Symposium on Electrets, Sept. 21-27, 1991 Berlin, Germany.
8. B.A. Mac Donald and B.G. Fallone\*, *Surface charge distributions on radiation charged electrets*, Proceedings of the 7th International Symposium on Electrets, Sept. 21-27, 1991, Berlin Germany.

9. B.A. Mac Donald\* and B.G. Fallone, *Precision in dosimeters employing radiation charged electrets*, American Association of Physicists in Medicine 34 Annual Meeting and Technical Exhibition, August 23-27, 1992, Calgary, AB
10. B.A. Mac Donald\* and B.G. Fallone, *Modeling of surface charge distributions on radiation charged electrets*, Annual Meeting of the Royal College of Physicians and Surgeons of Canada, Ottawa, Ontario, 11-14 September 1992.
11. B.A. Mac Donald\* and B.G. Fallone, *Decay characteristics of radiation charged electrets*, Annual Meeting of the Royal College of Physicians and Surgeons of Canada, Ottawa, Ontario, 11-14 September 1992.
12. B.A. Mac Donald\* and B.G. Fallone, *Radiation induced conductivity effects on electret-based personnel dosimetry*, Annual Meeting of the Royal College of Physicians and Surgeons of Canada, Ottawa, Ontario, 16-18 September 1994.
13. M.D.C. Evans\*, E.B. Podgorsak, M. Pla, L.J. Schreiner, B.G. Clark, B.A. Mac Donald and C. Pla, *Dosimetric characteristics of surface applicators for high dose-rate brachytherapy*, Annual Meeting of the Canadian College of Physicists in Medicine and the Canadian Organization of Medical Physicists, June 4-7, 1995, Montreal, QC
14. M. Gosselin\*, M.D.C. Evans, B.A. Mac Donald, M. Pla and E.B. Podgorsak, *Equivalent square as a predictor of depth of dose maximum for megavoltage therapy beams*, Annual Meeting of the Canadian College of Physicists in Medicine and the Canadian Organization of Medical Physicists, June 4-7, 1995, Montreal, QC
15. B. Keller\*, V.J. Pisciotto, and B.A. Mac Donald, *A treatment device for the simplification of total body irradiation*, Annual Meeting of the American Association of Physicists in Medicine, July 21-25, 1996 Philadelphia, PA

### Poster Presentations to Research Conferences

1. L. Ryner, B.G. Fallone and B.A. Mac Donald, *The development of an electret dosimeter*, American Association of Physicists in Medicine 32 Annual Meeting and Technical Exhibition, July 22-26, 1990, St. Louis, MI.
2. B.A. Mac Donald, B.G. Fallone and L.N. Ryner, *Charge distribution and stability on the radio-charged electret*, American Association of Physicists in Medicine 32 Annual Meeting and Technical Exhibition, July 22-26, 1990, St. Louis, MI.
3. B.A. Mac Donald and B.G. Fallone, *Surface charged distributions in radiation charged electrets*, American Association of Physicists in Medicine 33 Annual Meeting and Technical Exhibition, July 20-26, 1991, San Francisco, CA
4. B.G. Fallone, B.A. Mac Donald and L.N. Ryner, *Characteristics of a radiation charged electret dosimeter*, Proceedings of the 7th International Symposium on Electrets, Sept. 21-27, 1991 Berlin, Germany.
5. B.A. Mac Donald and B.G. Fallone, *Surface charge distributions on radiation charged electrets*, Proceedings of the 7th International Symposium on Electrets, Sept. 21-27, 1991, Berlin Germany.
6. B.A. Mac Donald and B.G. Fallone, *Precision in dosimeters employing radiation charged electrets*, American Association of Physicists in Medicine 34 Annual Meeting and Technical Exhibition, August 23-27, 1992, Calgary, AB

### Invited Presentations

1. B.A. Mac Donald, *The Physics of Prostate Brachytherapy*, New San Juan Health Center Workshop in Prostate Brachytherapy, April-16, 2000, San Juan, Puerto Rico

2. B.A. Mac Donald, *High Dose-Rate Prostate Brachytherapy, The Clinical Experience*, The Tri-County Brachytherapy Discussion Group of South Florida, October-5, 2000, Boca Raton, Florida

Referees:

1. Ervin Podgorsak, Ph.D.  
Department of Medical Physics  
Montreal General Hospital  
1650 Cedar Ave  
Montreal, QC H3G 1A4  
(514) 934-8052
2. Brenda Clark, Ph.D.  
B.C. Cancer Agency  
Medical Physics Division  
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3. Vince Pisciotto, M.S.  
Radiation Physics Inc.  
3590 South State Road 7  
Suite 2  
Miramar, FL 33023  
(305) 537-1319
4. Steve Edwards.  
Vice President of Clinical Operations  
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5. Human Resources  
Salick Health Care, Inc  
Mt. Sinai Comprehensive Cancer Center  
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