



Association of Imaging Producers & Equipment Suppliers
European Industrial Association for Nuclear Medicine and Molecular Healthcare

AIPES NEWSLETTER 2018



A nuclear medicine milestone: AIPES celebrates its 30th birthday in 2019

The date was May 5, 1989. That was when three radiopharmaceutical producers met to talk about the legal issues concerning the growing field of nuclear medicine. Their encounter 30 years ago marks the origin of our association. Today AIPES boasts more than 40 companies - from multinationals to SMEs - and our association is recognized around the world as the platform of the nuclear medicine industry in Europe.

Over the years we have managed various challenges, promoted innovation and delivered results. We aim to ensure that our products and practices are updated as new techniques and technologies emerge. We encourage dialogue: many nuclear medicine pioneers are still on board at AIPES, working with the newer players in the world of imaging.

As we approach our 30th anniversary, which we will celebrate at our next General Assembly meeting in May 2019, we realize that we still have a long way to go. But we are ready for the journey, with new projects, new ideas and your invaluable support. Once again, we would like to express how much your trust and confidence motivates us to go even further.

With our very best wishes to all of you, representatives of the AIPES General Assembly, and the members of the working groups,

Jocelyne Baldasso, Administrator
And the Executive Committee

Dear AIPES members, Dear colleagues and friends,



On behalf of the AIPES executive team, I would like to thank you for all your contributions and your support in 2018.

The end of the year is always a reflective time. It is a moment for taking stock of what we did with the time allotted to us. This AIPES newsletter shows us once again that our association is a constant in the changing world of nuclear medicine.

It is also a time to recognise the impressive growth of nuclear medicine over the past few years, as new equipment and radiopharmaceutical products have been developed. They have paved the way for personalised and targeted medicine, offering new solutions in fields like oncology, neurology, and cardiology.

One of the biggest obstacles to nuclear medicine is the widespread public belief that nuclear power is itself dangerous. Many people still make a link between nuclear medicine and radioactive fallout, perhaps imagining that our imaging machines are about to leak or even explode. These ideas may be quaint, but they are pervasive.

AIPES believes in nuclear medicine and is committed to showing patients, medical doctors and decision makers how it can improve patient management, how it is safe, and how it can respond to the unmet medical needs in the coming years.

Thanks to your support and your ideas, AIPES is today an essential platform for nuclear medicine, giving various communities (patients, physicians, decision makers) the opportunity to discuss its many benefits.

Our newsletter summarizes the work we have done this year and the changes in our world. Even after 30 years – and despite our busy working lives and our limited budget - we remain as committed as ever to nuclear medicine. We have redesigned our structure and set up a dedicated cell for European relations. Konrade von Bremen has been named as our European Liaison Officer: she will be at the forefront of the European policy decisions in molecular imaging and will work to strengthen relations with the EU.

Our efforts have helped to establish AIPES as a player in nuclear medicine. AIPES is a great association and we can congratulate ourselves for its achievement in supporting the industry. And all of this would never have been possible without the motivation of our working groups, their leaders and the general assembly who supported our decisions.

Of course, a lot remains to be done. My colleagues on the Executive Committee and myself, at the end of our three-year mandate, are confident that there will be new sources of creativity, invention and innovation over the next year.

A special thank you to my colleagues of the Executive Committee, Antonis Kalemis and Angel Hijos, with whom it is a real pleasure to work. I would also like to give very special thanks to Jocelyne, who is a guarantee for the continuity, creativity and professionalism at highest level within the AIPES organization.

I will step down from my position of AIPES President at the next General Assembly and I want to express my thanks for your support and how happy and proud I have been in chairing our association.

It only remains for me to wish AIPES an ever brighter future.

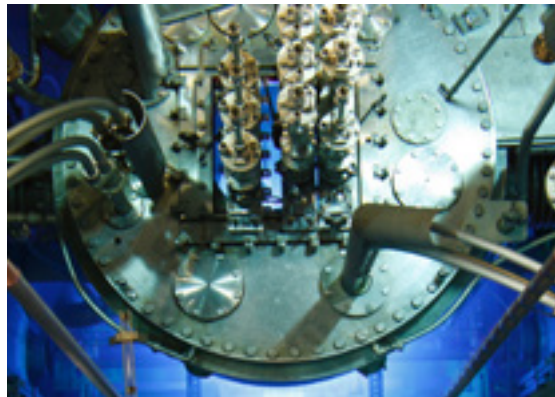
With my best wishes for a successful year 2019

Michael Nader,
President, AIPES

A tough year but a happy ending: NTP Radioisotopes back in production

Following a year-long shutdown, South African isotope manufacturer NTP Radioisotopes (NTP) resumed production in mid-November, after securing the approval of the South African National Nuclear Regulator (NNR).

NTP, which is a state-owned company and a subsidiary of the South African Nuclear Energy Corporation (Necsa), is a major global supplier of Mo-⁹⁹ and I-¹³¹. Its production plant was shut down by the NNR in November 2017 following a safety-related incident where a hydrogen monitor was found to have been incorrectly calibrated. Necsa appointed an interim management team in an attempt to return the plant to service. However, NTP underestimated the scope of work and the time it would take to address the situation to the satisfaction of the NNR. The shutdown would lead to local and global shortages of Mo-⁹⁹ and I-¹³¹.



During NTP's absence, AIPES played a key role in mitigating the impact of NTP's outage on the global market by coordinating supply through its Emergency Response Team consisting of reactor operators, isotope producers and generator manufacturers. AIPES also directly approached the South African government to highlight the urgency of the situation and call

for a positive resolution. In September, the South African Ministry of Energy assumed direct oversight of the NTP Board and worked closely with returned NTP executives and the NNR to facilitate the successful return to service. The resumption of NTP's operations was announced by NTP Chair Dr Namane Magau and Group MD Tina Eboka, who also commended the efforts of NTP's engineers and the technical and regulatory staff.

In early December the South African Energy Minister Mr Jeff Radebe replaced the entire Necsa board, including its Chair and CEO, appointing former Necsa CEO Rob Adam as the new Necsa Chair, and former NTP MD Don Robertson as the acting CEO of Necsa.

Since the restart, NTP has been successfully manufacturing product and supplying its customers, although it is currently operating at a reduced capacity as a first phase before resuming full production early in 2019. The company is confident that it will return to its former position as a reputable, safe, and reliable isotope manufacturer, led by an even stronger team under Group MD Mrs Eboka, which is closely aligned with the new Necsa leadership, and the NNR, and which has the fullest support of the South African government.

Spotlight on the Regulatory Affairs, Quality and Health Policy Working Group

As the year is ending, it is good to look back and review the accomplishments of the AIPES Regulatory Affairs, Quality and Health Policy Working Group (RA&Q) over the last 12 months.

And for the RA&Q, 2018 was above all a year of growth. It now has a total of 23 members representing 20 companies, making it the largest RA&Q group in AIPES' history. It includes many experts from different backgrounds in regulatory affairs, quality, reimbursement, and health policy. The group's growth reflects the activity in the field over recent several years: many radiopharmaceuticals have been approved across Europe and there is a growing pipeline with several members developing both at the radiopharmaceuticals level as well as at the equipment level.

This was also a year of firsts. The RA&Q group has worked with the European Association of Nuclear Medicine (EANM) to comment on the European Medicines Agency's (EMA) draft guideline on Good Manufacturing Practice (GMP), providing an industry position on the proposed text. The group received an invitation from the EMA to take part in a roundtable discussion about Brexit last September, with one representative of the group attending the session. Some group members attended events hosted at the European Parliament, as well.

These are great opportunities for the group, as representatives of this industry, to provide an industry position and perspective in future regulatory developments. The group encourages all members to take part in these activities – and there are more coming in 2019.

We can already expect 2019 to be a busy year for the RA&Q group, as several activities are currently being planned. The group aims to raise its visibility amongst regulators and other groups in the imaging and pharmaceutical fields and the group is also planning to draft an industry position paper on the reimbursement of radiopharmaceuticals in Europe.

To simplify exchanges within the group, a sub-group has been formed, which will meet every month to discuss topics of common interest for all our members and will communicate with all members. The sub group is represented by Hatice Erkan (Monrol), Cristiana Gameiro (IBA), Joana Brilhante (ANMI), Helen Barker (Blue Earth Dx), supervised by AIPES President Michael Nader.

We look forward to a fruitful 2019 for our industry and more great achievements for the RA&Q group.

AIPES sets up Reactor Schedule Facilitator tool for secure reactor exchanges

The screenshot shows a web browser window with a login and validation form. The form includes the following fields and buttons:

- Login:** A text input field containing "email@address.com".
- Password:** A password input field with masked characters "*****".
- SUBMIT:** A green button.
- password forgotten?:** A small link below the password field.
- Token:** A text input field containing "XXXX".
- VALIDATE:** A green button.

The exchanges between research reactors producing the vital Mo-99 isotope are sensitive and confidential.

In an effort to reinforce these exchanges while ensuring their security, AIPES Executive Committee commissioned a sophisticated computer tool allowing stakeholders to send their information in complete confidentiality.

The tool is now ready: AIPES is pleased to announce the creation of the Reactor Schedule Facilitator (RSF), which will be operational from January 2019. This is a great advance that will allow a regular update of the changes in the production line of the various reactors.

The screenshot displays the main interface of the Reactor Schedule Facilitator (RSF) tool. It features a calendar view for selecting reactor availability and a bar chart showing production levels.

Interface Elements:

- Select your reactor's availability:** A section with tabs for the years 2017, 2018 (selected), and 2019.
- Calendar:** A grid of monthly calendars from January to December. The 2018 calendar is active, showing production levels for each day. Some days are highlighted in orange, indicating specific production events.
- Quantity (Ci):** A text input field with a value of "2200".
- SAVE:** A green button.
- SUBMIT:** An orange button.

Bar Chart: A bar chart at the bottom shows production levels for each day of the year. The x-axis represents days (2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31) and the y-axis represents quantity in Ci. A red horizontal line indicates the "Minimum Ci" level. The bars are blue, with some orange bars indicating production events.

An emergency response that lasted a whole year

The AIPES Emergency Response Team (ERT) probably had its busiest year since its creation in 2013. This was due to two lengthy outages of the NTP Radiopharmaceuticals (South Africa) Mo-99 and I-131 production facility that took place in 2018 (see separate story). The NTP outages, which occurred from mid-November 2017 until mid-February 2018, and then again from early June 2018 until mid-November 2018, had an intermittent and negative impact on the international supply of Mo-99 through the year.

The AIPES ERT discussed it in teleconferences on an almost weekly basis for most of 2018. The ERT received regular updates from NTP to monitor its efforts. These included its interactions with the National Nuclear Regulator of South Africa on authorisation to return to service and on the ability of the other major Mo-99 suppliers to compensate for the loss of NTP production. The ERT also coordinated, where possible, actions by other supply chain partners to take mitigating actions to prevent international Mo-99 shortages.

The NTP outage highlighted the inadequate spare capacity in the global Mo-99 supply chain: the loss of a major Mo-99 processor could not be fully compensated. In addition, certain inefficiencies were also evident in the supply chain: in some cases, commercial or regulatory reasons meant that available Mo-99 could not be used by prospective generator makers. Capacity also fell because of delays in various projects that had anticipated increased activity from existing producers as well as initiation of production from new producers.

With NTP now back online, the outlook appears much more positive for 2019. In addition, the new ANSTO Australia Nuclear Medicine (ANM) facility is about to begin commercial production. The ERT now hopes that it can take a long nap in 2019 - and will not be disturbed by more interruptions in global Mo-99 production!



The efforts of the ERT - which gathers representatives of Mo-99 processors, research reactors, and generator manufacturers - has been exceptional, helping to ease the problems linked to the shortage, and ensure hospitals continued to offer vital patient care.

Kevin Charlton, OECD/NEA (Nuclear Energy Agency) expressed that « the work performed by the AIPES Security of Supply (SoS) Working Group to co-ordinate reactor availability and the Emergency Response Team (ERT) work to investigate, initiate and monitor actions to mitigate against supply problems were strongly appreciated in 2018 by the OECD-NEA High-level Group on the security of supply of Medical Radioisotopes (HLG-MR). 2018 was a difficult year with many extensive challenges to supply and the work and communications from the SoS and ERT were invaluable in allowing the OECD-NEA HLG-MR to keep international stakeholders and governments around the world fully informed of the situation. Communication was on a near weekly basis throughout the year and it was a testament to the flexibility and resilience of the AIPES members that disruption was able to be minimised throughout the majority of the period. The OECD-NEA looks forward to continuing to work cooperatively with AIPES during 2019. »

Pierre Dejonckheere named chairman of the Transport Experts



The Transport Experts Working Group has spent many months focusing on the Brexit implications for the transport of radiopharmaceuticals. The group is in continuous discussions with the EMA and other national and European entities to consider all scenarios, including possible custom barriers.

After six successful years in the job, Rob Dekkers has stepped down from his position as chair of the group. He does not, however, leave the ship and will continue to work within the group, representing GE HC. The whole community is very grateful for his service.

His successor is Pierre Dejonckheere, who will take up his post on January 1, 2019. Juul Rijpkema will remain vice-chairman and will support the group.

We wish Pierre all our best in his new role. This important group will have to face difficult challenges in 2019 and we thank him for accepting the responsibility.

The latest Innovation Focus looks at FDG

The latest Innovation Focus, the periodical from the Innovation Working Group, was published. It is entitled, FDG - the radioactive sugar that changed cancer diagnosis.

FDG is the most commonly used tracer. It launched PET imaging and has transformed cancer patient management over the past 20 years. This mature technology can still be a key player for future innovation, according to the experts interviewed in this newsletter.

The Innovation Working Group is preparing a new periodical entitled, SPECT – the present and the future, as well as a tribute to the pioneers of nuclear medicine, to be issued in the first half of 2019.

- [Click here to download *Innovation Focus : FDG: The radioactive sugar that changed cancer diagnosis*](#)
- [Click here to download the Hygieia poster](#)

Strengthening the work of the Nuclear Medicine Awareness Working Group

The Nuclear Medicine Awareness Working Group (NMAW) group was created in 2010 and today its messages are shared on major social networks and translated into a dozen languages. We will continue this approach, especially in cases when the general public wants information about our discipline.

NMAW Vice-Chair Maryam Khodaverdi had a meeting with the EANM President and the EANM Executive Committee at the EANM Congress in Dusseldorf in October 2018 to discuss potential areas of collaboration.

EANM has now launched a one-year pilot project focusing helping patients become much more informed so they can take ownership of their therapy. If the pilot turns out a success, the idea is to build up patient engagement in a structured way. It follows a UK model, and EANM has engaged an UK expert in the field in order to explore the viability of this public and patient involvement project.

At Dusseldorf, EANM and the NMAW agreed to further discuss how to merge forces for planning and performing related activities together. New ideas, new challenges are envisaged for 2019, among others, a new animation explaining the theranostics concept.



*The animated version of the successful leaflet
«Will I glow in the dark?» is now online!*

AIPES Symposium shows how molecular imaging is changing healthcare as we know it

AIPES organized its annual symposium at the historic Solvay Library on March 26, 2018, entitled **Guided Cancer Management for European Citizens**. Top practitioners, researchers, economist and decision makers discussed how new molecular imaging techniques could now show detailed pictures of tumours and other issues, and how the image accuracy is giving doctors precise tools to identify and treat cancer growths.

The event was supported by the European Parliament's Committees for Health and Industry, which has a strong interest in cancer research. They have invited our association to organize its next symposium in the Parliament's premises, in the presence of the various MEPs.

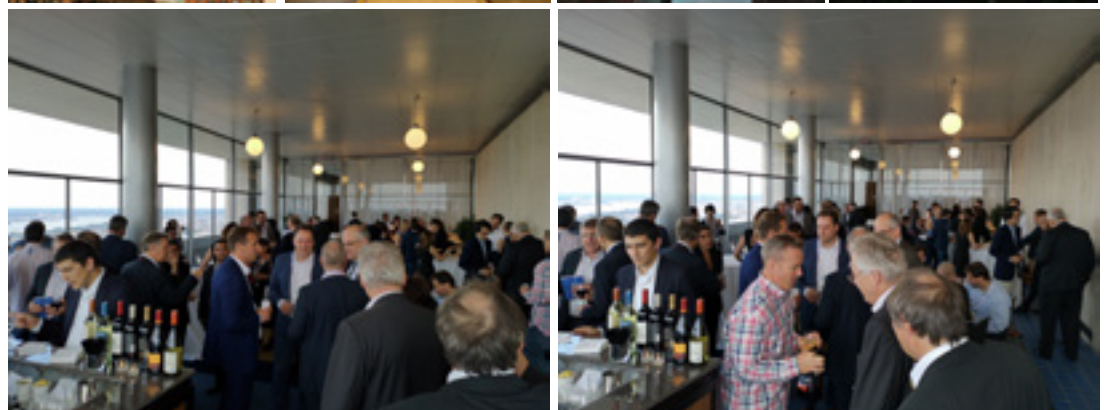
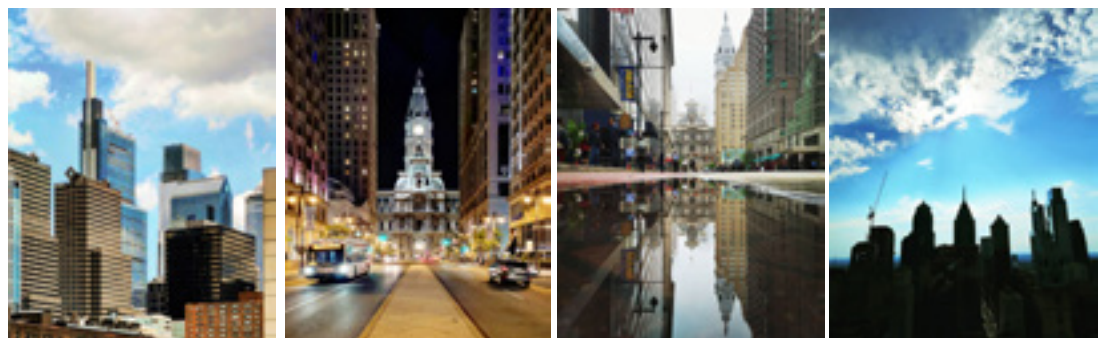
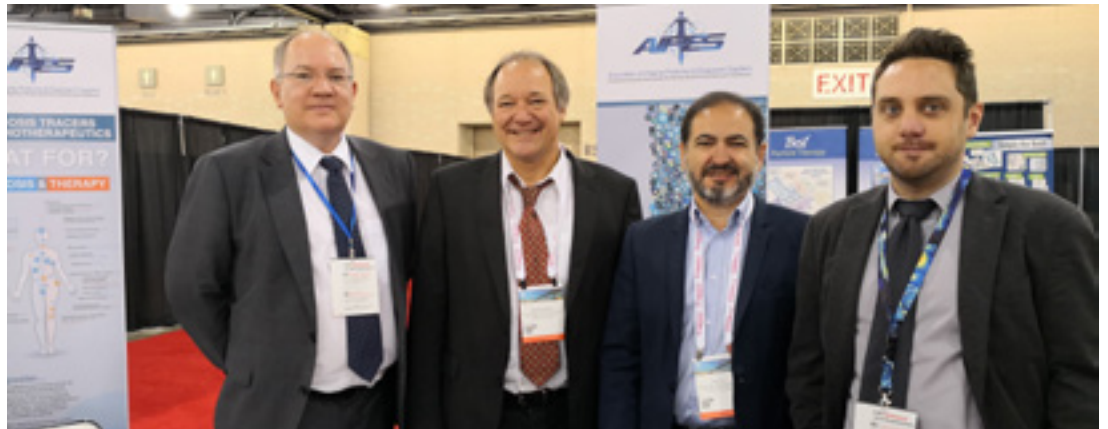


AIPES WORLDWIDE: Mission to Philadelphia for the 2018 SNMMI meeting

It is always a pleasure for the European nuclear medicine industry to take part in the annual meeting of the Society of Nuclear Medicine and Molecular Imaging (SNMMI). It is a moment to meet our partners from the other side of the Atlantic and to share our information with our American alter ego.

It is also an opportunity to meet our members, discover their latest products and projects, and make new contacts.

The SNMMI meeting in Philadelphia in June 2018 was a networking success, and we celebrated our contribution at our evening cocktail, on the 26th floor of the Loews Philadelphia hotel.



Polatom and the MARIA Reactor host European Observatory

The European Observatory on the Supply of Medical Radioisotopes was invited by the research reactor MARIA and the company POLATOM to hold one of its meetings in their premises in Warsaw. It was also an occasion for AIPES visit the reactor and the radiopharmaceutical laboratory.

We enjoyed the hospitality of our guests and their organisation, who gave us - and representatives of the European Commission's Joint Research Centre - a full briefing on how they operate.



EUROPEAN OBSERVATORY
on the supply of medical radioisotopes



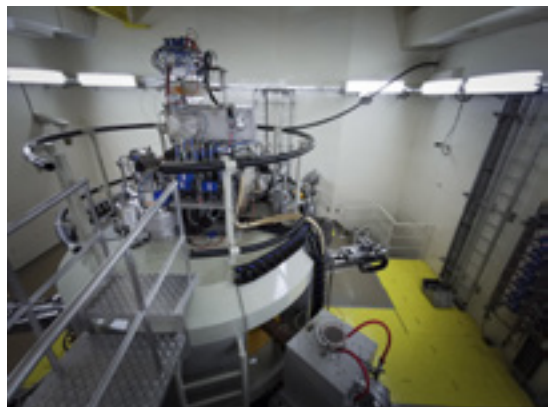
Dusseldorf hosts the 2018 EANM Congress

The European Association of Nuclear Medicine (EANM) held its 2018 congress in Dusseldorf, gathering 180 companies and associations and 6,250 visitors. AIPES made sure that its booth was there too, and distinct from the medical associations, in order to better communicate with our partners of the industry. The evening event at the Steigenberger Hotel gathered 110 guests.



AIPES welcomed by our Japanese Associate Partner

During a stay in Tokyo, David Crunelle (AIPES Corporate Identity) was kindly invited to visit the Fujifilm facilities in Chiba, where he was detailed all the specificities of running a cyclotron. A very interesting experience with the particularly elegant hospitality of our partners.



AIPES Newcomers



ATLANPOLE BIOTHERAPIES is an interregional cluster, first recognized and certified by the French Ministry of Industry in July 2005.

It co-ordinates the work of laboratories, companies and platforms for public-private solutions in the bio-medicine value chain, from target discovery to clinical evaluation. Atlanpole supports Isotop4Life, a state-funded initiative to endow the west of France with a genuine industrial sector open to international trade – the aim is to equip the Clinic of the Radio Immuno Therapy (RIT) to take in patients from all over the world. Atlanpole Biotherapies is represented at the AIPES General Assembly, by **Jean-François Gestin**, Founder of Isotop4Life.

It joined AIPES as a full member in May 2018.

<https://www.atlanpolebiotherapies.eu>



NUCLEIS Radiopharmaceuticals is a spin-off from the University of Liège, Belgium, created to outsource the manufacturing and distribution of PET radiopharmaceutical drugs.

The company's core business consists in the manufacturing of market authorised drugs and Investigational Medicinal Products (IMPs). NUCLEIS is developing a wide portfolio of diagnostics tools in order to support the emergence of innovative therapies. It is represented at the AIPES General Assembly by CEO **Fabrice Giacomelli**.

They joined AIPES as a start-up (associate member) in May 2018.

<https://nucleis.eu>



TRASIS

TRASIS

Jean-Luc Morelle and Gauthier Philippart founded Trasis in 2004 to focus on what matters: innovation, quality and proximity.

Trasis equipment is used worldwide in nuclear medicine departments, research centres, radiopharmaceutical production facilities and pharmaceutical companies. The company is dedicated to helping the medical community to access new radio-labelled therapeutic and diagnostic substances easily and faster. It designs, manufactures, sells and supports high performance synthesizers, dose preparation equipment, shielding and accessories.

The company also develops customised synthetic methods and instruments. Trasis can provide GMP Active Pharmaceutical Ingredients (API) and help the customers with their regulatory affairs.

Trasis joined AIPES on May 2018 as a full member and is represented at the AIPES General Assembly by **Jean-Luc Morelle**.

<http://www.trasis.com>



AIP- Advanced Innovative Partners

With its European business located in Bad Berka, Germany, AIP is a radiopharmaceutical company focused on the development of novel therapeutic and PET imaging agents in oncology, neurology and rare paediatric diseases with the aim to deliver transformative science to underserved and paediatric patients.

AIP joined AIPES as a full member on May 2018 and is represented at the AIPES General Assembly by Chief Strategy Officer **Andrew Satz**.

<https://www.advancedinnovativepartners.com>



THANK YOU ALL!



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