

## Paving the Way to the Best Sustainable Molecular Healthcare Model in Europe



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

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## About AIPES

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AIPES (Association of Imaging Producers & Equipment Suppliers) brings major nuclear medicine pharmaceutical laboratories together with major medical equipment producers for this medicine area. Members include multinationals as well as local medium size companies.

Nuclear medicine is based on radiopharmaceuticals associating drugs with short-life radio-nuclides that, once injected into the patient, enable 3D imaging, using state-of-the-art cameras, in important pathologies such as cancer and heart or brain dysfunction. In oncology, radiotherapeutic applications also demonstrate high efficacy and generate an increasing interest among physicians. The defense and promotion of key players in this highly regulated discipline require an integrated organization such as AIPES.



AIPES has existed since 1989, and represents the interests and aspirations of the nuclear medicine and molecular imaging healthcare industry. AIPES is governed by an executive committee consisting of senior executives from the nuclear medicine industry. The Committee implements strategic decisions with the support of five Working Groups, constituted with highly qualified representatives in their specific fields of activity. These representatives from each member company are mandated by the group, to work on regulation policies to strengthen Europe's global nuclear medicine and molecular imaging objectives.

The administration office, based in Brussels, is in charge of coordination between stakeholders, and acts as a liaison office and an information platform between the Group and the other European entities.

AIPES brings together scientific, technical, legal and policy experts to develop solutions to legislative and regulatory issues affecting the nuclear medicine industry. This collective knowledge allows AIPES to provide advice and assistance to policy makers and legislators in European Union institutions: the Council, the Parliament and the Commission. In particular, AIPES was the initiator of - and plays a major role in - the European Observatory for Isotopes Supply, put in place by the Commission following the worldwide Molybdenum shortage crisis.

In addition to its role as provider of a forum for addressing specific radio-pharmaceutical issues similar to CORAR in the US, and its role as an industrial partner to the European Association of Nuclear Medicine and any other European medical society that could help in the promotion of diagnostic imaging, AIPES aims to communicate medical potential and latest technical developments to the public in the field of nuclear medicine.



## Our Mission

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### Enhancing Imaging and Therapy with Molecular and Radioactive Tracers

## Our Objectives

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- Foster Innovation in nuclear medicine and molecular imaging;
- Cooperate for appropriate regulations in all aspects of nuclear medicine missions;
- Support and facilitate our members' logistics and operations needs;
- Promote the value of nuclear medicine achievements.

## Our Role

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### EU Lobbying: a Keystone in the European Building

#### EU Lobbying: a Keystone in the European Building

28 countries where more than 500 million people live with an average life expectancy of 78 years and speak over 200 languages: that is how impressive the European Union is. In order to regulate very technical subjects, European Union Authorities need and seek professional expertise and advice. Nowadays, lobbyists are well respected stakeholders involved in EU decision-making processes. The European Union has chosen to institutionalize lobbying. This benefits everyone. The involvement of private stakeholders in the EU decision-making process provides EU legislative and regulatory authorities with information over some highly technical issues. This guarantees that the wording included in final legislation reflects the balanced interests of all public and private stakeholders.

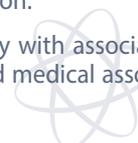
In addition to traditional players in the field of molecular medicine, AIPES stays in close contact with political and regulatory European Authorities (members of the European Parliament, of European Commission Directorates and Medical Agencies), as well as with the media and patient associations.

AIPES is recognized as the privileged interlocutor between the European Union and industry representatives in the field of radiopharmaceuticals, molecular imaging systems and related medical equipment. The growing interest of EU representatives and of Member States Authorities for Health and Energy strengthens the role of AIPES in this field.

The clinical potential of molecular healthcare involves many aspects regulated by the EU. AIPES daily monitors numerous European decision making processes which impact members' activity and patient wellbeing. In 2012, the association participated along with the European Commission to the creation of the "European Observatory of Isotopes Supply". This Observatory addresses the security and supply of medical isotopes in Europe, in particular all Molybdenum supply crisis-related issues. The AIPES Reactor & Isotope Working Group is central for this Observatory.

Being part of the current imaging diagnostics revolution; through AIPES, the nuclear medicine and molecular imaging industry wants to provide the public with relevant and compliant information.

AIPES regularly coordinates its activity with associations such as CORAR, COCIR, JRPA and medical associations like EANM and SNMMI.



## Working Groups

### AIPES Activities are Supported by Five Working Groups:

#### 1. Regulatory Affairs

To analyze draft legislation pieces and monitors their adoption by the EU legislator. Moreover, the Group lobbies the EU and Member States' authorities involved in the regulatory process for radiopharmaceuticals and related equipment marketing authorizations while taking into account patient safety and environment regulations.

#### 2. New Technologies

To assess the consequences of new technologies in all nuclear medicine and molecular healthcare processes.

#### 3. Reactor and Isotope

To coordinate current and future solutions for the supply of necessary radionuclides in radiopharmaceutical applications.

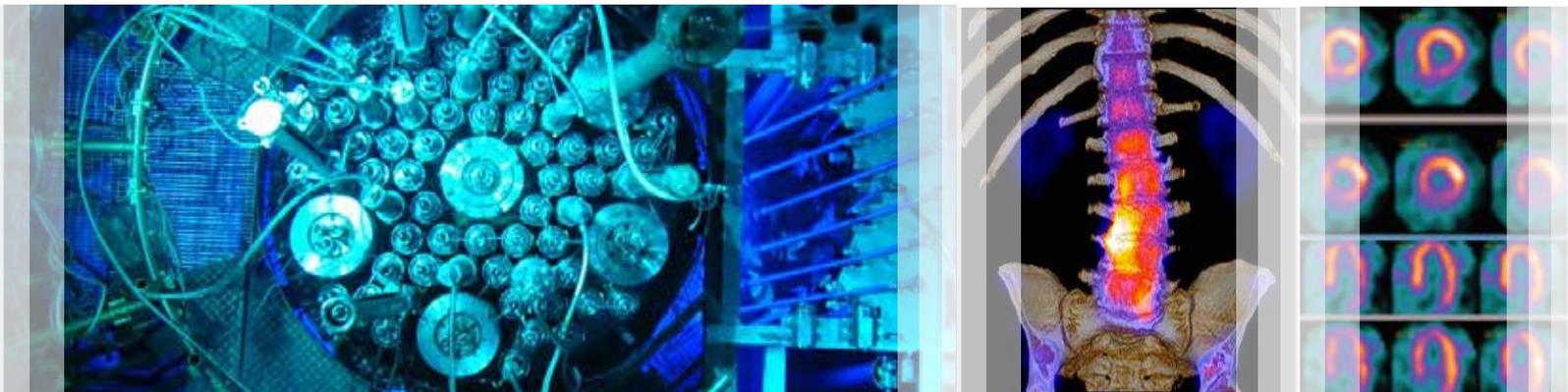
#### 4. Transport Experts

To cooperate with regulators for worldwide road, air or sea transportation of radioactive materials.

#### 5. Nuclear Medicine Awareness

To communicate all relevant information regarding nuclear medicine and molecular healthcare to all communities, EU, governments, agencies, physicians, patient groups and the public.

Member Companies work together within AIPES to forge industry consensus on the challenges and opportunities which arise in the European policy area. Issues are carefully analyzed and positions are developed and decided by the many experts that compose each of the five main working groups.



## 1. Regulatory Affairs

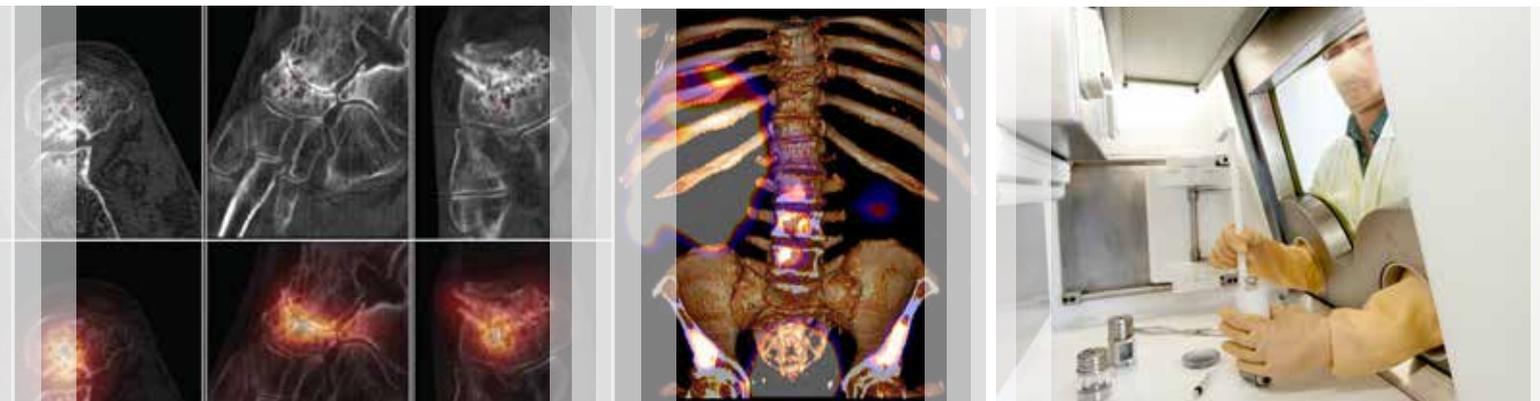
The AIPES Regulatory Affairs Expert Group represents member companies on current, pending and proposed pharmaceutical legislation, regulations, specific guidelines, etc.

The Expert Group plays a significant role in permanently monitoring these pending and proposed documents on both national and EU level.

If certain issues are liable to impact our business, the group may take proactive lobbying actions to the European Parliament, the European Commission, national and EU competent health authorities, as relevant. The group drafts position papers and aims to influence the decision making via its contacts with key regulatory and legislative staff.

On a regular basis, it provides members with news and relevant documents issued by EU institutions and affiliated committees concerning pharmaceutical legislation and market issues. The Expert Group discusses regulatory topics of mutual interest and aims to find common response ground for the authorities.

Since its creation, the Regulatory Affairs Expert Group has gained increasing importance and has successfully completed important lobbying actions.



## 2. New Technologies

Nuclear Medicine is a unique clinical medicine branch in modern healthcare systems. Similar to other medical specialties, nuclear medicine aims at providing diagnostic tools and therapeutic options to patients worldwide. As such, nuclear medicine is based on the use of radioactively-labeled functional imaging agents, as well as the use of complex technologies and imaging systems. Over the past decade, nuclear medicine-based imaging systems have become dual-, and even multi-, modality imaging systems (as PET-CT, SPECT-CT or PET-MR), thus turning nuclear medicine into a rapidly evolving part of diagnostic and therapeutic medicine.

“New Technologies” is a Topical Working Group within the AIPES Organization, aiming to provide a gateway to detecting and understanding new technological developments in the field of non-invasive imaging and therapies involving radionuclides. Selected members of imaging and pharmaceutical industries set up the New Technologies Working Group with extensive background in applied and advanced imaging.

The Working Group receives input from its members on new technological and associated developments worldwide, and, together with the AIPES Executive Committee, highlights those developments to all AIPES members. In view of the rapid advances and significant changes in nuclear medicine, the group develops educational activities and provides teaching materials for the Nuclear Medicine community. In close collaboration with the AIPES Executive Committee, the group monitors EU Research initiatives and advises AIPES members on resulting potential support activities.

Furthermore, the group informs AIPES members on topics of interest from the nuclear medicine community, and initiates - as well as supports - survey activities. In addition, the group liaises with complementary working groups or committees within other European organizations to support technological and radiopharmaceutical research, training and development with a particular focus on projects and strategies towards personalized, image-guided therapy planning, delivery and monitoring.



### 3. Reactor & Isotopes

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The Reactor & Isotopes Working Group brings together AIPES members who operate Research Reactors or use their output for medical isotope production purposes. This Working Group has been officially established as the reference body for coordinating the licensed reactors' worldwide schedule in order to provide a sustainable supply of medical radionuclides.

The main goal of this Working Group is to achieve optimum period coordination during which the different Reactors are operating, in order to provide adequate global coverage throughout planned reactor shutdown periods for refueling and maintenance. This coordination is necessary to ensure mother isotopes production continuity as well as supply of final Radiopharmaceutical products and Therapy sources to hospitals all year round. The Working Group also provides a forum for Research Reactor operators and Radiopharmaceutical producers to keep each other informed about important developments in the medical isotope market and to discuss issues of common concern.

The production of Molybdenum-99 (Mo-99) in particular is very sensitive to any unplanned unavailability of Reactors. In Nuclear Medicine, around 80 % of all diagnostic procedures (approx. 30 million per year) depend upon Tc-99m, the decay product of Mo-99. Both Mo-99 and Tc-99m have short half-lives; this excludes the possibility of building buffer stocks of these important materials.

Initially, the Working Group concentrated on European Reactors. But following various recent events which identified that the supply situation was becoming more difficult, and in view of the global scope of Mo-99 supply, it became clear that this group had to extend its sphere of activity to include all global reactor operators and distribution organizations: e.g. NRU in Canada, SAFARI in South Africa and OPAL in Australia.

In order to maximize the Working Group's efficiency, Research Reactor operators became associate members of AIPES in 2009. Therefore they are now full participants in Working Group meetings and this, combined with the increase in the number of participating Reactors, has contributed to a smoother and more open dialogue. The Working Group - assisted by the AIPES Executive Committee - has numerous contacts with European Institutions as well as individual National Authorities. The Working Group also cooperates with the OECD NEA group and supports the IAEA in global initiatives to solve current and future Mo-99 supply problems. The Working Group also built close working ties with medical associations such as the European Association of Nuclear Medicine (EANM) and the Society of Nuclear Medicine and Molecular Imaging (SNMMI), as well as with parallel industry groups such as CORAR in the USA.



## 4. Transport Experts

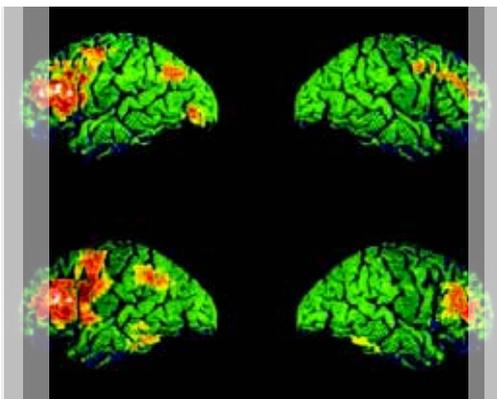
Safe transportation of Radiopharmaceutical Products is a vital requirement for the daily practice of Nuclear Medicine. The radioactive material needs to be transported safely and efficiently to meet this need. To this aim, a number of different parties must comply with a set of regulations that can be open to interpretation.

With the purpose of proactively addressing radioactive products transport-related issues, AIPES members have created an ad-hoc Transport Expert Working Group. The group was set up to have a common understanding and to define standards within the radiopharmaceutical industry throughout Europe for safe radioactive materials transport globally.

These standards, used by the group for shipment, package checking, carrier control and audit, are fundamental for radioactive material control. All members adopt these standards for major aspects pertaining to radioactive products transportation.

### Original Main Aims:

- define a common understanding of how we can guarantee transport safety and improve our standards whilst maintaining transport costs within acceptable limits
- define common ground for discussion with the Authorities on transport safety-related issues, and for focusing future regulations on issues that really matter
- define a common standard to be implemented by all carriers
- define a possible platform for designing respective areas of responsibility and control with air carriers to avoid duplication of efforts, possibly through an audit procedure
- set up procedures to check parcel compliance before they leave manufacturing premises
- share package return standards with the European Association for Nuclear Medicine (EANM).



## 5. Nuclear Medicine Awareness

If Nuclear Medicine plays a key role in the current imaging revolution going on for new diagnostics, it remains a complex discipline to be explained to all stakeholders. Very few people are aware of all the workings and possibilities of this technique. Moreover, even fewer people know about the high potential of radiolabeled molecules in therapeutic applications, which may change the way of treating cancer patients, among others, in a very near future.

The recently formed Nuclear Medicine Awareness Working Group created by the AIPES assembly aims to provide the most up-to-date factual information on Nuclear Medicine and Molecular Imaging to all potential stakeholders: including European Union Commission, referring physicians, patient groups and lay press to name a few.

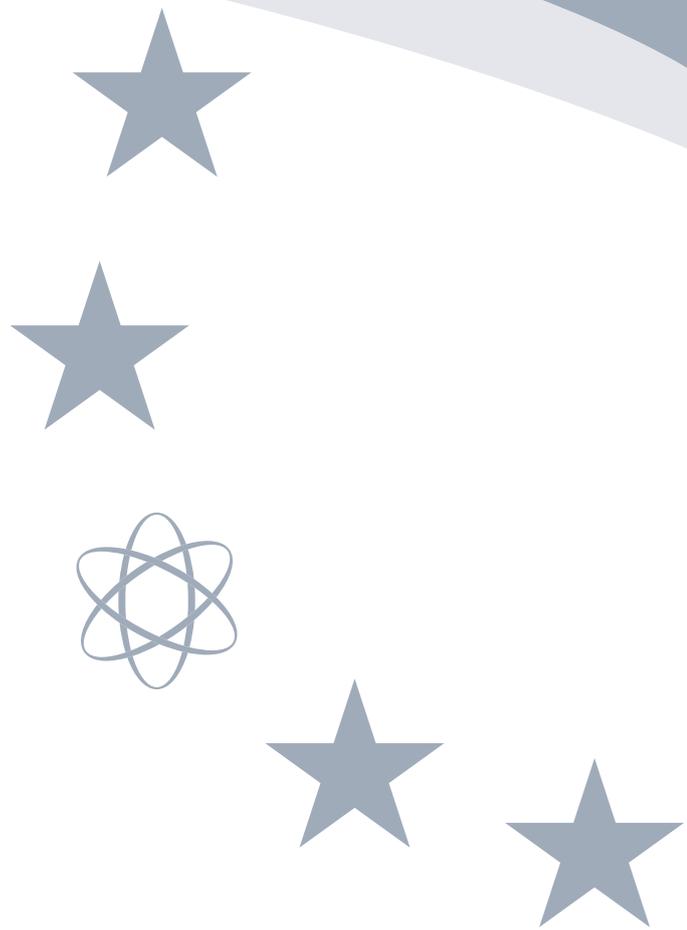
The website [whatisnuclearmedicine.com](http://whatisnuclearmedicine.com) offers information covering basic as well as innovative aspects of nuclear medicine, and its animation takes a patient or stakeholder on a journey from radiopharmaceutical production to imaging and diagnosis.

The website also offers more detailed information on heart, brain and oncology imaging techniques, along with a Q&A section addressing major FAQs. The website is a continual work in progress. It aims to provide a factual and up-to-date reference site for those who are not familiar with Nuclear Medicine.

In all our communication initiatives, the team works closely with Nuclear Medicine experts and in close collaboration with the EANM.

Be it the web, leaflets, press releases or awards, the Working Group strives to give a balanced view of the modality's role and benefit in order to raise awareness to the European Community and beyond.





**Picture credits:**

AAA, IBA, IRE, Dr T. Kuwert - University of Erlangen , Dr. M. Lonneux - Group CHIREC, General Electric, Lemerpax, Medisystem, Philips, SCK-CEN, Siemens.



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