COVID-19 Pandemic: Supply of Medical Radioisotopes and Radiopharmaceuticals

Thursday, April 23, 2020, 14.00 – 15.30 CET
Mr Joao Osso, from Brazil holds the degrees of Ph.D. in Nuclear Chemistry from the University of Manchester, England, M.Sc. in Nuclear Engineering from the Federal University of Rio de Janeiro (UFRJ), Brazil and B.Sc in Chemistry from the University of Sao Paulo (USP), Brazil. He had more than 34 years of experience in the field of radioisotope and radiopharmaceutical production in Brazil before joining IAEA in February 2014. He is currently the Head of the Radioisotope Products and Radiation Technology Section from the Division of Physical and Chemical Sciences at the International Atomic Energy Agency (IAEA) in Vienna, Austria.
Melissa Denecke is the Director of the Division of Physical and Chemical Sciences in the Department of Nuclear Sciences and Applications at the International Atomic Energy Agency in Vienna.

She is a radiochemist and an internationally recognised expert in application of state-of-the-art techniques for radionuclide characterisation on a molecular scale using a number of laser- & accelerator-based and research reactor techniques.
Dr. Diana Paez Gutierrez is the Head of the Nuclear Medicine and Diagnostic Imaging Section, Division of Human Health, Department of Nuclear Sciences and Applications at the International Atomic Energy Agency (IAEA).

Born in Bogota, Colombia. Graduated in Medicine and Surgery at the Faculty of Medicine of El Bosque University, with a degree in Nuclear Medicine from the National Cancer Institute, Javeriana University in 1994. Attended fellowship trainings in nuclear cardiology at the St. Luke’s-Roosevelt Hospital and in Nuclear Oncology (PET) at the Memorial Sloan Kettering Cancer Centre in New York, USA in 1997. She holds a master’s degree in Communication and Education from the Autónoma University in Barcelona, Spain.

Dr. Paez places special emphasis on strengthening the competences of nuclear medicine and diagnostic imaging professionals worldwide. Dr Paez has published over 60 book chapters and articles in scientific journals. She is an avid lecturer, participant on scientific panels and has chaired numerous symposia and scientific meetings as scientific secretary.
COVID-19 Pandemic - Webinars

- Challenges for Nuclear Medicine Departments - 25 March
- Guidance for Nuclear Medicine Departments - 16 April

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COVID-19 Pandemic: Guidance for Nuclear Medicine Departments

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7. Department of Nuclear Medicine, Chonnam National University Medical School, Hwasun, South Korea
8. PET/CT Department at Quanta Diagnostics and Therapy, Curitiba, Brazil
9. Humanitas University and Humanitas Research Hospital, Milan, Italy
10. Department of Nuclear Medicine, Universitätsklinikum Essen, Essen, Germany
11. Department of Molecular Imaging and Therapy, Austin Health, Melbourne, Australia
12. Ahmanson Translation Imaging Division, David Geffen School of Medicine at UCLA, Los Angeles, California
Ram Charan Sharma - IAEA

Ram is a chemical engineer and has 37 years of experience of working in Bhabha Atomic Research Centre, Mumbai, India, in all aspects of research reactors from design to decommissioning. He is currently working as the Acting Section Head and Project Manager, Research Reactor Operation and Maintenance in the Research Reactor Section of International Atomic Energy Agency. He is responsible for management of section activities and providing technical support to Member States in enhancing availability and reliability of their operating research reactors.
Radioisotope Production in Research Reactors for Global Supply : COVID-19 situation

• Major producers (RRs) of Radioisotopes were contacted through email to know the status and later a website has been created to enable them to upload the information directly:
• Most of the RRs have introduced measures to limit the effect and spread of COVID-19 and continued production of radioisotopes to meet the demand.
• Some RRs completed scheduled shut down jobs and preponed reactor start up to resume radioisotope production.
• Many RRs are operating to meet internal demand.
Radioisotope Production in Research Reactors for Global Supply: COVID-19 situation

- Major RRs in operation:
  - BR-2, Belgium;
  - HFR, Netherlands;
  - OPAL, Australia
  - SAFARI-1, South Africa
  - MARIA, Poland

- Production Schedule adjusted to cope with reduction in demand due to transportation difficulties.
- RRs in RF are working in accordance with plans, including the production of medical radioisotopes.
Mr. Joao Osso, from Brazil, holds the degrees of Ph.D. in Nuclear Chemistry from the University of Manchester, England, M.Sc. in Nuclear Engineering from the Federal University of Rio de Janeiro (UFRJ), Brazil, and B.Sc in Chemistry from the University of Sao Paulo (USP), Brazil.

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• RPRT Section: Activities related to production of medical radioisotopes and radiopharmaceuticals:
  • Webinar:
    – Requests from MSs regarding supply of RI, RPh (TC purchases)
    – Questions from previous webinars promoted by NMDI Section
  • Decision: last Friday
  • Contacts: Institutions and companies from MSs
  • Not possible to have more panelists
  • 18 short presentations from IAEA (2NA, NE, NS), 3 Associations, 5 companies, 8 Institutions, 1 Physician
• First request: El Salvador: Instituto Salvadoreño del Seguro Social
  – Weekly demand: I-131 2,300 mCi; Tc-99m 3,000 mCi (3 generators every 2 weeks), MDP 10 vials, MAA 2 vials, DTPA 5 vials, MIBI 10 vials, Nanocoloides 5 vials

• Survey
  – Total: 65 replies from 45 Member States (all regions)
  – 51 normal operation
  – 36 problems with import of RI
  – 21 problems in supplying NM centers
  – 57 with extra measures (safety of staff)
  – 27 with transport issues
Mr Bernard PONSARD holds the degrees of Master of Science in Physics and Master of Science in Nuclear Energy from the Catholic University of Louvain, UCL, Belgium.

He joined the Belgian Nuclear Research Centre (SCK CEN) in 1985 as reactor physicist at the BR2 High-Flux Material Testing Reactor. In charge of the neutronic calculations of the BR2 reactor core for 30 years, he moreover actively developed the commercial production of Radioisotopes and NTD-Silicon.

He is currently Stakeholder Manager for the production of Radioisotopes and NTD-Silicon at the BR2 reactor, including the strategic development of new radioisotopes for nuclear medicine and industry, and new products for the semiconductor industry within SCK's Institute for Nuclear Materials Science.

He is also Deputy Chairman of the “Nuclear Medicine Europe Security of Supply Working Group”, strongly involved in securing the Global Supply of Medical Radioisotopes as Mo-99/Tc-99m, Chairman of the “Nuclear Medicine Europe Emergency Response Team” (ERT) for the crisis management of the Radioisotope Supply Chain, and Co-Chairman of the "European Observatory on the Supply of Medical Radioisotopes".
What is Nuclear Medicine Europe and what is the function of the Emergency Response Team (ERT)?

✓ Nuclear Medicine Europe (NMEu) – « The Industry Association » represents the major actors of the Nuclear Medicine industry and their interests in Europe, supporting the medical community delivering state-of-the-art healthcare to patients.

✓ Its ‘Security of Supply’ Working Group coordinates the irradiation capacity of the 6 major reactors (BR2, HFR, LVR-15, MARIA, SAFARI, OPAL) involved in the Mo-99 production to secure the continuous supply.

✓ The ERT (Emergency Response Team) has been created in 2012 within the NMEu ‘Security of Supply’ Working Group to follow production and supply issues through conference calls in case of emergencies related to the supply of Mo-99 and other medical radioisotopes.

✓ The ERT is composed of 4 technically knowledgeable decision makers, each respectively emerging from reactors, processors, generators manufacturers and transport.

The current ERT Team:

For the reactors: Bernard Ponsard, Chairman, SCK CEN
For the Processors: Frank De Lange, Curium
Jean-Guy Dronneau, IRE
For the Generators: Ira Goldman, LMI
For Transport: Gilles Degauque, Transrad
Rapporteur: Jocelyne Baldasso, NMEu
What is the information gathered by ERT regarding the supply of medical radioisotopes during this situation?

✓ The ERT held already 10 weekly conference calls since the 9th of February to manage the COVID-19 crisis and try to mitigate its impact on the supply of medical radioisotopes globally.

✓ Herewith the outcome of the last ERT call held on 20 April, 2020:

- The estimated decrease of the Mo-99 demand is currently about 20%
- The production of Mo-99 remains under control
- The air transportation is the most significant bottleneck for shipping orders to customers
- The producers have modified their processing schedules to better align with available flights
- Discussions are ongoing with KLM to initiate transport - upon approval by their regulators - beginning April 27 for an initial five week period
- NMEu continues to advise that logistics difficulties create short-term risk on the security of supply of both bulk Mo-99 and Tc-99m generators, but no specific shortages are presently foreseen.
Are there any changes in the operation of BR-2 Reactor and the production of Mo-99?

✓ On 18 March 2020, a ministerial decree was published in the Belgian Official Journal containing the government’s urgent measures to reduce the spread of the COVID-19 coronavirus. The decree listed nuclear and radiologic sector activities, such as the production of radioisotopes, as essential services. Guaranteed operations at SCK CEN are therefore considered as important.

✓ The BR2 reactor operated by SCK CEN is a major facility for the global supply of radioisotopes (Mo-99, Lu-177, ...).

✓ With an installed irradiation capacity of 7500 '6-day' Ci per week, the BR2 reactor is currently (in 2020) able to supply at least:

- 40-50% of the global Mo-99 demand (9000 Ci ‘6-day’ Ci/week) in average
- 85% in peak periods

✓ Suitable measures have been taken to maintain the reactor fully operational.
✓ No production issues at reactor level, but the logistic is very challenging!
Mr Ira N. Goldman, Senior Director, Global Public Policy and Government Relations, Lantheus Medical Imaging (USA), holds a Masters of Arts in International Affairs from the Johns Hopkins School of Advanced International Studies (Washington, DC).

Chairman Nuclear Medicine Europe Security of Supply WG; Co-Chairman, CORAR Isotope Supply Committee; 40 years experience in international nuclear matters including medical radioisotopes and nuclear medicine. Previous positions with the International Atomic Energy Agency (Vienna, Austria); the U.S. Department of Energy (Vienna and Washington DC), and the U.S. Department of State.
You are the chairman of the Security of Supply Working Group (WG) of NME. What is the function of the WG? What are the major findings in this period?

- European Industrial Association for Nuclear Medicine and Molecular Healthcare – “working together to improve molecular healthcare.”

- Security of Supply WG includes research reactors, Mo-99 producers, and Tc-99m generator manufacturers.

- Coordinate research reactor schedules to provide adequate global coverage year-round including during planned reactor shutdowns for refueling and maintenance.

- Emergency Response Team (ERT) has held weekly telecons to monitor supply chain actions to maintain production during COVID-19 pandemic and to communicate with external stakeholders (European Commission, OECD/NEA, etc.)

- Disruption of normal passenger air flights has led to international transportation challenges especially transatlantic and Europe-South Africa which led to cancelled and delayed flights, radioactive decay loss. Mo-99 producers have changed production schedules due to separate production teams and to match flight availability.
Has the production and distribution of Tc-99m generators by Lantheus been affected during this situation?

- Round-the-clock efforts to track and manage ever-changing flight schedules.
- Re-arranged manufacturing schedules with short notice to adjust to the continual transportation changes.
- Increased charter aircraft to expedite customer deliveries.
- Frequent communications with customers in regard to adjusted generator shipments and schedules.
What is the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) and what is its role related to the supply of medical RIs and RPhs?

-Council on Radionuclides and Radiopharmaceuticals, Inc.: “….advocates for regulations and legislation that facilitate the growth and viability of its member companies.”

-Proactive agenda that includes education of U.S. Congress and regulatory bodies on benefits of radiopharmaceuticals and radionuclides used in medicine and life sciences.

-18 member companies (including major domestic Mo-99 projects), Board of Directors, 5 committees on Isotope Supply; Transportation; Healthcare Policy; Nuclear Pharmacy; and Manufacturing, Health, and Safety.

-Weekly teleconferences during COVID crisis to coordinate efforts to address medical isotope transportation problems especially actions with US Government.
Panelist

Nelson To – Hong Kong

• Mr. Nelson To from Hong Kong holds the degrees of MBA from the University of London, England.
• BSc. In Chemistry from the University of Hong Kong, Hong Kong
• He has more than 10 years experience on the field of radio-isotopes sales & marketing on both medical device (radio-embolization) and pharmaceuticals (SPECT and PET products)
• He is one of the founder of the company and currently work as the General Manager of RIT Biotech Co. Ltd. - a central-radiopharmacy in Hong Kong. He is focused on local supply chain, compliance and new product launch.

LinkedIn - linkedin.com/in/to-nelson-20195936
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As a central radiopharmacy in a MS with high Covid-19 impact, how are you operating the production of radiopharmaceuticals?

Maintain Clean-room standard and office cleanness
Consumables shortage:
  e.g. IPA (Iso-propyl alcohol), bleaching solution, high standard face masks, sterile gowning
  Source from local pharmacies, and international companies

Working hours – being flexible
  No affect for production staff (mid-night work), flexible for normal hours staff to avoid peak hours traffic

Compounding and dispensing services
  No change on services, suffer higher cost due to low patients services. E.g. only 1 - 2 patients per centre

International Communication and reaction efficiency
  Work from home policy
    Suppliers are not able to confirm the schedule on productions / shipments / QC support, cannot access data base for information

Raw materials supply for radiopharmaceuticals production
Consumables
  Stock control for important supply chain products e.g. O-18 water with higher purchasing amount
Did you face any problems importing and distributing the required radioisotopes during this pandemic. If yes, how do you manage with your customers? Answer: Definitely, YES

**Mo-99/Tc-99m Generator**

Engaged with delay on deliveries, multiple suppling sources are necessary. The best would be to consider which reactors are supplying Mo-99 to the manufacturer. E.g. IRE for Monrol, OPAL for ANSTO

For international airline disturbance, here are the actions we are working on:

Shifting the shipment by :
1) Changing airline service
2) Shifting from passenger flight to cargo flight
3) Changing suppliers (at least buying from 2 suppliers for a stable period)

**I-131 Capsules**

Same as Mo-99 / Tc-99m generator, however we suggest end-users should have an early plan on treatment e.g. booking the case 3 - 4 weeks before. Calibrate higher activities for the patients, more buffer days for shipments and deliveries.

**O-18 water supply and other consumables**

Expected delay for all shipments, increase the stock level
What extra safety measures are you taking for operating your facilities during this time?

Preventive measures
- Forehead Thermometer measurements before entering the office / lab
- Staff is not allowed to work if they have fever
- Encourage staff to have sick leave if they are not feeling well
- Spread alcohol onto the clothing before entering into the office
- Encourage to have lunch in the office rather than outside
- Use hand sanitizer frequently

Protective clothing
- All staffs should wear face mask: compulsorily
- Logistic drivers need to wear gowning during delivery
- Encourage staff to wear glasses or googles

Production Team / Sales & Marketing team
- Try to separate teams into 2 offices (Team with in-door work and out-side work)
- Avoid the Sales & Marketing team to visit hospitals, shift the communication to WhatsApp, telephone, online meeting and teleconference
Putthiporn Charoenphun – Thailand

Ms Putthiporn Charoenphun holds the degrees of Ph.D. in Imaging Sciences and Radiation Biology from King’s College London, UK, M.Sc. in Biochemistry from Mahidol University, Thailand and B.Sc. in Associated Medical Sciences from Chiang Mai University, Thailand.

She has more than 25 years of experience on radiopharmacy in Thailand. She is currently a lecturer in Master of Science Programme in Medical Physics and Head of Radiopharmaceutical laboratory, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Thailand.
Looking at the Covid-19 situation, how has the operation of your facility for production of radiopharmaceuticals been affected quantity-wise?

**Previous:** On-site $^{99}$Mo/$^{99m}$Tc generator + SPECT and PET tracers unit doses

**Now:** One generator (500mCi) per week is sufficient and cyclotron produced radiopharmaceuticals are available.
How did you manage to get the required radioisotope supply during this time?

MANAGEMENT

Outside country

• Vendors in Thailand change the suppliers or flights

Inside country

• Collaboration among centers to share technetium-99m
What extra safety measures are you taking for operating your facilities during this time?

- Separate into 2 teams, working different working days
- Protect against infection (such as surgical mask and glove)
- Physical distancing and monitoring temperature everyday
Mr René Leyva Montaña, from Cuba holds the degrees of M.Sc. in Nuclear Chemistry from Technical University of Prague, Czech Republic, M.Sc. in Radiochemistry from the High Institute for Nuclear Sciences and Technology of Havana, Cuba and Ing. in Nuclear Chemistry from the Technical University of Prague, Czech Republic.

He has 30 year of experience on the field of radioisotope and radiopharmaceutical production in Cuba. He is an international IAEA expert with several missions in Latin America, Africa and Asia. He is currently the **General Director of the Isotope Centre** from Cuban Nuclear agency and advanced technology.
What is the status of the production and distribution of RIs and RPhs in Cuba?
CENTIS also exports RPhs, but has it stopped now?

CENTIS is the most complex radioactive facility in Cuba. CENTIS offers a wide variety of products, including labelled compounds, radiopharmaceuticals, radioisotope generators and conventional and radioisotopic diagnostic reagents, which are suitable for medical, agricultural and industrial purposes, as well as for genetic engineering and biotechnology.
Generators production in Cuba

- Until 2003 generators imported from different suppliers (Amershan, CIS, NORDION)
- Generator production started in 2003.
- More than 4000 units produced in the last 5 years.

- Supply to the regional market (Dominican R., El Salvador, Nicaragua (IAEA TC), Honduras, Costa Rica, Ecuador, Jamaica and Venezuela)
René Leyva Montaña – Cuba

Generator hot cell line

CUB/6/023

Jack hoist table for the bulk-Mo-99 transport into the dispensing box

Glove box for final assembling of the inactive sterile generator
INVITATION

International Symposium on the Occasion of 25th Anniversary of CENTIS.

Havana, Cuba
9-11th December, 2020
Mr. Efrain Perini holds the degree of Ph.D. in Nuclear Technology Applications from the University of Sao Paulo and M.Sc and B.Sc. degrees in Mechanical Engineering from the Sao Paulo State University, Brazil. He had worked in R&D at the Brazilian Navy Technological Center and in 2010 joined the Brazilian National Nuclear Energy Commission (CNEN/IPEN). Currently, he is the Head of Radiopharmacy Centre of IPEN/CNEN in Sao Paulo, which supplies 90% of the radiopharmaceuticals in Brazil. He has experience with radioisotopes and radiopharmaceuticals productions and has collaborations with the Brazilian Multipurpose Reactor (RMB) project.
Brazil has a big demand for RIs and RPHs, but is it dependent of imports? What is the status of the production and distribution in Brazil, your Institute in particular?

Medical RIs in Brazil: ~ 100% imported
Thus, the situation of the production with COVID-19 is:

1. Collaborative work with IPEN, CNEN and several ministries succeed in bringing Mo-99 and I-131 from South Africa (NTP) on April 6th. Nowadays: Mo-99 and I-131 from Russia (Rosatom) and Mo-99 from Holland (Curium) weekly.
2. Demand on RPs from NM services: reduced ~50%
3. IPEN and the Brazilian NM Association: to prioritize Mo-99/Tc-99m generators, I-131 and Lu-177 supply.
4. IPEN extraordinary production of Ga-67 and Tl-201: logistics being provided by Curium/Amy.
5. Distribution: prioritize ground transportation (lack of national regular flights)
6. Distribution main problem: supply chain (national and international flights)
What actions were necessary to keep the routine production and the supply to NM centers?

1. IPEN declared RPs production as “essential service”:
2. Task force to continue productions every week: logistics details, track every flights, RI producers are very collaborative to solve supply logistics. The key: great and collaborative team and intense communication.
3. IPEN strategy and recommendation:
   a) To announce each RPs production only if the RI (flight) took off at its origin (or at connection).
   b) List of essential consumables and services to keep the production and quality control during this period
   c) Plan and advanced the supply calendar of packaging (Type A) and other consumables;
   d) Personnel/Staff: we asked our employees who have chronic diseases to stay home. Productions are carried out with specific and constrained work shift during limited period.
4. To export the casks (B(u) containers): reverse logistics challenges (limited flights)

Special thanks to IPEN essential services teams, CNEN, ministries, Brazilian Nuclear Medicine Association (SBMN) and all IPEN/CNEN suppliers.
James T. Harvey – USA

Mr Harvey, from the United States, holds the degrees of Ph.D. in Nuclear Chemistry from the University of Arkansas, and B.Sc in Chemistry from the University of Virginia.

He has almost 50 years of experience in the field of radioisotope production, use and management in the US. He has been the Chief Science Officer at NorthStar Medical Radioisotopes, LLC, located in Beloit, WI USA, for the past 15+ years.
I presume some NorthStar employees are working from home. Does it affect the operation of your facility for production of radioisotopes? Is it affecting centralized radiopharmacies?

Yes, some NorthStar employees are working from home. NorthStar production is Considered Critical Essential Infrastructure: 1/3 work as “Normal”; 1/3 partial work from home; 1/3 completely work from home. To date, production of domestic Mo-99 has not been affected at any of our locations. Support from the staff at MURR has continued to be outstanding. We have established additional in plant safety and hygiene measures to protect staff. We do see Radiopharmacy demand is down ~50% due to delay/cancellation of elective testing.
I believe you are shipping the domestic Mo-99 and generators to the US customers on a weekly basis. Does the COVID-19 affect transportation of radioisotopes in the US?

NorthStar is shipping regularly each week to customers, with no misses so far. We have not experienced any COVID-19 transportation delays to date but we have a unique transportation supply chain with dedicated currier service.

NorthStar Medical Radioisotopes, LLC

RadioGenix® System 1.2
(technetium Tc 99m generator)

Approved by US FDA on 1 October 2019
Which problems do you envision in the US radioisotope market if the pandemic continues?

Risk of 40-50% procedures being significantly delayed or cancelled which will impact hospital and Radiopharmacy revenues. We are concerned this challenge may lead to closures and possible bankruptcies, especially among smaller independent Radiopharmacies.
Panelist

Oğuz Ergun – Turkey

Mr Oğuz Ergun, from Turkey holds the degree of BSE in Industrial Engineering from Gazi University, Turkey. He has 7 years of experience on the field of radiopharmaceutical sales and logistics. He is currently the Head of the International Sales Department in Eczacıbaşı Monrol.

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As a major producer in the region, what is the major issue for providing the MS with your product?

The major issue for us was the cancellation of all passenger flights of Turkish Airlines which was the major source for us to deliver our products all over the world. Now they’re expanding their cargo flight network and we’re trying to adapt this new situation.

On the other hand, different restrictions of different countries such as completely closing the customs, curfew applications and/or switching the major hospitals to the Pandemic Centers naturally limited us to supply.

The total effect of all is around 50% decrease on our deliveries all around the world as you may see from the map.
As a major producer in the region, what is the major issue for providing the MS with your product?
Which radiopharmaceuticals are more affected, cyclotron based ones or others?

It depends to each country but generally I could say the others. Cyclotron based ones are mainly affected from the switching of Major Hospitals to the Pandemic Centers, but still in this case the patients could go to the other alternatives.

There is one important exception for this for us in Turkey, that the PET numbers are dramatically decreased as well.
What is your plan for upcoming months? If the market demands start growing again, what are the priorities?

We have very strong and strategic partnership with Turkish Airlines and working very closely with them in this term as more than ever. It means we’re closely following the daily changes in cargo flight schedules and trying to reach everyone all around the world to inform them once we’re ready to supply even if they’re our current customers or not. This brings us additional supply opportunities instead of our losses.

As reply to your question, we’re expecting to reach our normal levels again around mid August with the current trend of disease and the help of the additional affects I mentioned.

For the following question; our priorities are health of our employees and sustainability of our supply in this term.
Panelist

Antero Abrunhosa – Portugal

First degree in Biochemistry and MSc in Biomedical Engineering from the University of Coimbra, Portugal.

PhD work at the MRC - Cyclotron Unit, Hammersmith Hospital in London, UK (1996-2000).

Currently Director of the Institute for Nuclear Sciences Applied to Health (ICNAS) a leading facility in Portugal for Nuclear Imaging based at the University of Coimbra.

EDQM (European Pharmacopeia): Member of Expert Group 14 (Radiopharmaceuticals)

IAEA: Expert in several Technical Committees and Field Missions.
Can your center produce and distribute RPHs during this period?
What measures have you taken to protect your staff, both in the Cyclotron and in the Radiopharmacy operations?

Nuclear Medicine Technologist @ ICNAS
Emergency ventilator – Open source!

- Low cost
- Common gas components
- Easily producible worldwide
- Projects ongoing in Angola, Brazil and Malawi.
Prof. Andrew Scott is Director of the Department of Molecular Imaging and Therapy, Austin Health; Laboratory Head at the Olivia Newton-John Cancer Research Institute; and Professor of Medicine, University of Melbourne, and La Trobe University. His clinical and research interests are focused on developing innovative strategies for targeted therapy of cancer with monoclonal antibodies, and in molecular imaging, particularly oncology applications in PET in staging cancer, as well as global issues of nuclear medicine and human health. His laboratory has been involved in the preclinical development and first-in-man trials of numerous recombinant antibodies in cancer patients, and seven antibodies developed in his laboratory have been licenced to Biotech and Pharma companies. He has over 360 peer reviewed publications, and numerous grants from National and International funding bodies.

He is the past-President of the World Federation of Nuclear Medicine and Biology, and is on the Board of many significant organisations including the Australian Nuclear Science and Technology Organisation (ANSTO), Chair of the Board of Cancer Trials Australia, and member of the Federal Council and Chair of the International Relations Committee of the Australian and New Zealand Society of Nuclear Medicine (ANZSNM).
Do you consider that nuclear medicine departments should continue their routine operation during the COVID-19 pandemic?

| Establish simplified purpose-designed governance and coordination mechanisms |
| Identify context-relevant essential services |
| Optimize service delivery settings and platforms |
| Establish effective patient flow (screening, triage and targeted referral) at all levels |
| Rapid re-distribution of health workforce capacity, including re-assignment of tasks |
| Identify mechanisms to maintain the availability of essential equipment and supplies |

WHO - COVID-19: Operational Guidance for maintaining essential health services during an outbreak
In your opinion, what essential services should nuclear medicine departments provide?

- NM should continue their operation
- Exert flexibility
  - Workplan to reinstate delayed services or events
  - Teaching activities virtual or postponed
  - Postpone non-essential procedures
  - Prioritize essential procedures (oncology, cardiology)
- Adapt patient appointments
  - Radionuclide therapies

Andrew Scott – Australia
How are you dealing with a supply of materials?

List of required supplies

List of all possible suppliers and distribution channels

Maintain a detailed inventory and to coordinate the redistribution of supplies
Mouldi Saidi – Tunisia

Mr Mouldi Saidi, from Tunisia holds the degrees of Ph.D. in Biochemistry/Radiotracers from the Pharmacy Institute Berlin, Germany, M.Sc. in biochemistry from Pharmacy Institute Berlin and B.Sc in physiology from the University of Orsay Paris, France.

He has more than 30 years of experience on the field of radiopharmacy and radiochemistry in Tunisia. He is currently professor and Head of the radiopharmacy department at the CNSTN / Tunisia, RAF/6054 project coordinator and since January 2019 Consultant in Isotope production and quality control.
Are you able to produce and supply $^{18}$F-FDG to NM units locally?

Instructions to be respected at the cyclotron facility for FDG production
Can you please tell us about the supply of Mo-99/Tc-99m generators and cold kits as well as I-131 therapeutic products?

**TRANSPORT BEFORE CONFINEMENT**

Production Site: curium, GE
Netherlands, Germany

- Dubai
- Tunisia

with Emirati company
transport index is = 10

2 days transport
Activity of a generator
= 840 mCi

*normal cost*

**TRANSPORT AFTER CONFINEMENT**

Production Site: curium, GE
Netherlands, Germany

- by car
- Maastricht
- by a cargo
- Istanbul
- by a cargo
- Tunisia

15 days transport
Activity of a generator
= 500 mCi

*very high cost*
Are there any measures taken collectively by concerned authorities in your country for an uninterrupted supply of these products?

Procedures have been loosened up for the provision of Generators and Iodine-131.

Weekly flight from GERMANY has been scheduled to ensure useful cargo.
Tamer Sakr – Egypt

Panelist

Associate Professor of Radiopharmaceutical Chemistry
QC Director of RPF-ETRR-2 complex-EAEA

Mr. Tamer Sakr, from Egypt holds the degrees of Ph.D. in Radiopharmaceutical Chemistry from the University of Ain Shams, Egypt, M.Sc. in Radiopharmaceutical Chemistry from the Helwan University, Egypt and B.Sc. in Pharmacy from Helwan University, Egypt.

He has more than 19 years of experience on the field of radioisotope and radiopharmaceutical production in Egypt. He is currently the QC director of the Radioisotope Production Facility (RPF) –ETRR-2 complex - Egyptian Atomic Energy Agency (EAEA), Egypt. He has 54 publications, 5 research projects and scientific team of 20 members in the field of radioisotope and radiopharmaceutical.

Email: Tamer_sakr78@yahoo.com
How are the operations of your RI production, especially Mo-Tc generators and their distribution for Egyptian NM centres, affected during this crisis time? How do you manage your staffing situation for these operations?
What problems do you envision in the near future to continue production?
Is your department proposing any mitigation measures to overcome the impact of current situation on RI and RPh production?
Neil G Hartman – United Kingdom

Neil Hartman holds a BPharm (Potchefstroom), an MSc in Nuclear Medicine (Stellenbosch) and a PhD in Clinical Oncology and Radiotherapeutics (Cambridge).

Neil currently is head of nuclear medicine and radiopharmacy at the Singleton Hospital in Swansea, and also a professor of pharmacy at Swansea University.

The Swansea Radiopharmacy manufactures radiopharmaceuticals daily for four nuclear medicine departments, and partakes in various aspects of research into novel ways of isolating blood products for cell labelling, and labelling mAb fragments with Zr-89 and V-48.
Looking at the severe covid-19 situation in UK, explain how do you continue the operation of your facility for production of radiopharmaceuticals?

• We operate our Radiopharmacy within full compliance of EU-GMP, and thus manufacture in pressurised cleanrooms with HEPA filters (grade C air), wearing full gowns, clogs, face masks and gloves. Demand has decreased, but we still complete a full manufacturing session each morning. In the cleanrooms, it does mean being in fairly close proximity to others, but wearing PPE.
• Outside the cleanrooms (in the rest of the Radiopharmacy) we try to adhere to at least 2 metres between staff.
How did you manage to purchase starting materials and supplies? Do you have a big stock of these supplies?

- The supply chain with regards to pharmaceutical supplies in the United Kingdom is working rather well.
- We purchase kits well in advance, and have standing orders for our Mo-99/Tc-99m generators.
- We purchase most radionuclides and kits from Curium and GE Healthcare, and they have been excellent in providing us with all we ask for.
- PPE and sterile gowns are also in good supply.
Are you able to supply the radiopharmaceuticals to the NM units?

Clinical demand has decreased considerably (perhaps 60% less requests; we are only scanning cancer and urgent cardiac patients, and emergency V/Q scans where we insist on a preference for perfusion-only scans), but we still provide a daily radiopharmaceutical service to all our client hospitals.
Mr Gilles Degauque, from Belgium holds a degree of Master in Economy from the University of Mons, Belgium.

He has been working at Transrad for more than 12 years where he has been acting as Operations Manager, Sales & Business Development Manager and now General Manager since September 2019. Transrad is a Belgian transport company active exclusively in worldwide radioactive and nuclear transports.

Since February 2020 Mr Gilles Degauque is also Chairman of the NMEU Transport Experts Working group.
WORKING GROUP TRANSPORT EXPERTS

• Define a common understanding of how we can guarantee the safety of transport and improve our standards whilst maintaining transport costs within acceptable limits.
• Define a common ground for discussing with authorities on transport safety related issues and for focusing future regulations on the really important issues.
• Define a common standard that we want 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.
• Define procedures to check parcels compliance before they leave a manufacturers premises.
• Returns standard shared with the European Association for Nuclear Medicine (EANM).

You are the chairman of the NMEu transport group. What are the functions of this group and what are the findings you have reported during the COVID situation?
Talking now as a Transrad representative, what issues are you facing nowadays? (1/3)
Talking now as a Transrad representative, what issues are you facing nowadays ? (2/3)

Road transport:

On one hand…

- Borders crossing take more time due to increased border controls (does not happen a lot to be fair).

- “Children diseases” regarding some admin docs.

- Promiscuity of drivers in one truck due to physical protection regulations.

On the other hand…

- A majority of European countries have extended the legal driving time in order to facilitate transports, France and Germany even allowed transport on Sundays and bank holidays for trucks (under normal circumstances this is forbidden).
Air transport:

- Number of flights available has decreased in a drastic way (flights within Europe and also flights going out of Europe to other continents).
Transport is a bottleneck on the supply. What can be done to improve the situation?

From Transrad’s perspective (= transport of non-irradiated U-235 targets and irradiated U-235 targets + transport of bulk Mo-99)

- Improve regulations uniformity: Patchwork of national regulations, sometimes difficult to cope with (ex. self-defence training, languages).

- Make access to air freight easier: increase the number of airlines accepting class 7. Develop charter air freight within Europe.

- Make everyone aware that costs for physical protection have increased for years now while transport rates remain stable.
Stephen Whittingham - IAEA

Joined the nuclear industry in 1980 in the design of BWR and PWR spent fuel casks, subsequently responsible for the safety cases and lead negotiator for licensing a fleet of PWR and BWR spent fuel casks for deliveries to the reprocessing plants in France and the UK.

Joined the UK Competent Authority in 2004, developed the compliance inspection programme for non-nuclear operators and was a member of the UK Government decommissioning and waste strategy groups. He has represented the UK in many international meetings.

During this time he served for two terms as Chairman of the European Association of Competent Authorities, which was formed in 2008 and a membership of 23 European States.

Stephen joined the IAEA in 2013 and is the Head of the Transport Safety Unit and the scientific secretary of the Transport Safety Standards Committee (TRANSSC).
Current situation

Based upon information received from ICAO and IATA

1. Significant reduction in air transport capacity, however
2. Many airline starting to use ‘passenger’ aircraft for cargo only flights
3. ICAO and IATA are actively involved with airlines and aircraft manufacturers and CAAs giving permission to make the change

Some carriers and airport operators are known to have refused Class 7 (radioactive) goods in the past

The current difficulties for transporting radioactive material is not due to radiation safety
ENGAGEMENT

a) Producers and users should monitor the situation and consider collaboration to engage with airlines to strengthen their existing carrier network as necessary

b) Involving the Government Health Departments and Transport Safety Competent Authority of the countries involved could be beneficial - in a way that demonstrates the independence of the competent authority (WHO / IAEA involvement)

c) Producers and Users should consider engaging with potential new carriers (WHO / IAEA involvement)

d) Producers, Users, Government Departments should consider to seek the possibility / benefits of being involved in the airline / airport operator engagement for airports en-route if this is the cause of refusal by airlines (WHO /IAEA involvement)
ENGAGEMENT

e) It may be considered helpful to avoid several separate approaches to an individual airline or airport operator;
   i. Perhaps a small delegation approach could be developed with IAEA, WHO, and Producer(s), Government Health Department(s) representing the stakeholders involved. (virtual meeting)
   ii. Competent authorities would be involved if subsequently needed

f) To identify candidate airlines we will need to know:
   i. the existing air freight carriers used during normal business
   ii. which routes are normally used
   iii. which of (i) and (ii) are not currently available
   iv. It would also be helpful to know which routes and carriers would the manufacturers like to use that were not available before the pandemic shutdown.
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Thank you!