

In this issue...

- Review of the 2019 UKRG Workshop.....[page 2](#)
- 2020 UKRG Workshop.....[page 3](#)
- Brexit Update.....[page 3](#)
- Adverse events.....[page 4](#)
- Full programme of the 2019 Ga68 for Beginners workshop.....[page 7](#)

Welcome to the Spring Edition of the UKRG Newsletter!

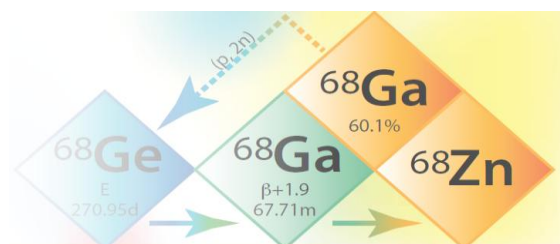
UKRG WORKSHOP: GALLIUM FOR BEGINNERS TO BE REPEATED IN EDINBURGH

After the success of the UKRG workshop "Gallium for beginners" held in London on 21st September 2018, the day is to be repeated in Edinburgh on **Friday 7th June**.

A link to register for the event is provided below:

<https://ukrg.meeting.org.uk>

This event was extremely popular, with places filling up quickly in London, so it was decided to repeat it in Edinburgh to give people who missed out another chance to attend. This event is open to everyone across the UK, and is to be held in Lecture Theatre 2, Chancellor's Building, University of Edinburgh, which is on the Royal Infirmary of Edinburgh site at Little France.



The programme has already been finalised and is reproduced at the end of this newsletter. As you will see, it is a packed programme, delivered by the

current experts in the field of Ga68 radiopharmaceutical production including UKRG members and their colleagues. In addition to this, it makes a great start to a weekend away in the beautiful city of Edinburgh!



Edinburgh – arguably the greatest city in the UK

If you are a site that are about to start a Ga68 service, or if you are considering starting up this service in the future, this study day will give you an unparalleled insight into how your colleagues that have been doing this for years, started up their service. Hear their helpful tips, learn from the challenges they faced, and most importantly, make connections with these experts for when you inevitably need help with something in the future.

Don't hesitate! Judging by last time, this will book up quickly, so visit the UKRG website and book today. We'll see you in Edinburgh on the **7th of June!**

UKRG TWITTER ACCOUNT



The UKRG has started up its own Twitter account, so if you can't wait for the latest news in Radiopharmacy and Nuclear Medicine to come out through this newsletter every few months, you can now get more frequent updates on Twitter.

We'll be posting more up to date news and events which occur more frequently than the newsletter is published and it might also be a great way to advertise vacant posts, so it's worthwhile following us on this platform.

The handle is **@UKRGnews**, so look us up and give us a follow!

#radiopharmacychat #UKRG #giveusafollow

UKRG BOURNVILLE WORKSHOP 2019

The 2019 UKRG workshop was held at Bournville on Friday 11th January 2019, thanks to the organisational work of Dr Neil Hartman and his team. After Neil's morning welcome, the morning session started with Dr Julian MacDonald, who talked about how to plan for a Nuclear Medicine therapy centre, with particular focus on radium-223. He gave a thorough presentation reviewing all the aspects involved such as logistics, approvals, legislation and also the facilities required. He shared his very valuable clinical experience and difficulties that he and his team had encountered over the last two years.



The second presentation of the day was about the impact that a no-deal Brexit could have on the importation of radiopharmaceuticals - a scenario that seems increasingly more likely by the day! Dylan Kerr from the Department of Health, highlighted how the Medicine Supply team was preparing for the worst case scenario to ensure the continuity of supply of medicines that are manufactured, batch tested, released or transported to the UK from Europe. As a contingency plan they have been in touch with all of the suppliers that import radiopharmaceuticals and radioisotopes to the UK. A number of contingency plans have been developed in collaboration with couriers to bypass the predicted congestion at the Channel Tunnel, including the use of air freight to deliver critical items such as Tc99m generators and short half-life radioisotopes. Curium and GE Healthcare have already started testing these transport routes in preparation for the UK leaving the EU.

Due to the increasing interest in PET scanning using gallium-68, there have been some challenges with the supply and availability of Ga68 generators and alternative PET radioisotopes are being investigated for potential clinical application. Professor Phil Blower explained the potential of scandium-44 for use in radiopharmaceuticals and how this could have some advantages over similar Ga-68 radiolabelled molecules. Scandium-44 has a half-life of approximately four hours, making it ideal

for Nuclear Medicine use, with a long-lived parent radionuclide in titanium-44, which has a half-life of 60 years. Professor Blower asked the audience if there would be demand for such products in the UK, but this was left in the air, to be evaluated by researchers, the pharmaceutical industry and the UKRG committee.

After the morning coffee break, where delegates could visit the industry exhibition, the workshop was resumed by Tim Sizer, who delivered a very interesting presentation, entitled Microbiology & Species Level Identification. Tim provided a great summary of the challenges involved in the identification of colonies in aseptic units, the expectations from a GMP compliance point of view and what to do once we have this information available.

One of the main challenges is to find the source of the contamination, so the Microbiology Protocols Group have reviewed the most common species of microorganisms found in clean rooms and have begun to develop a number of monographs describing them. An example of these monographs was published in the Christmas 2018 edition of the UKRG Newsletter and more are to follow in the future.



Tim did stress that these monographs do take a long time to write, with the evidence being occasionally conflicting, but it sounds like this will be a valuable resource in the future. At the moment, the only way to get hold of the few monographs that are approved, is to attend the Understanding Microbiology for Aseptic Services course, run by the University of Leeds in Bristol. This one day course runs once a year in April, so keep a look out for it through the University of Leeds website. There's a link below to where you'll be able to register for next year.

<https://engineering.leeds.ac.uk/short-course/2519>

Next up was Ian Harwood, GMDP inspector at the MHRA. His presentation was about the revision to Annex 1 and how this will impact radiopharmacies and aseptic units. While the final draft has not yet been published, Ian stressed that the major change has been the inclusion of Quality Risk Management principles throughout the document, aimed at identifying potential weaknesses in processes, and justifying decisions made through validation. Quality Risk Management should be at the core of what we do, so it was advised that we should start implementing it in our daily work, even before Annex 1 is published.

There was a very interesting discussion between Ian and some delegates regarding the identification of species seen on the previous presentation that exemplified the benefits of using a Quality Risk Management approach when dealing with Out of Specification results in grade B zones. Ian stated that a root cause analysis investigation should be performed on every out of specification settle or contact plate performed in a Grade A work zone, and that some effort should be made to determine if patients that were administered products prepared on that day had experienced in adverse effects that could be related to the presence of that organism in the environment on the day of production. The logistical feasibility of this was discussed, but the take home message was that before closing a CAPA report with “no impact on patients,” perhaps some investigation into whether there was an impact should be made first.

Another interesting presentation followed, delivered by Rav Seth from Micromedicine, who talked about how fully automated microfluidic technologies could help to separate and concentrate blood cells, prior to radio-labelling. Micromedicine have developed a commercial prototype of an automated cell separator that is available for trial, which improves the efficiency of blood cell radio-labelling, as well as significantly reducing the time and manual intervention required for the blood labelling process. For further information on this technology, visit www.micromedicine.com.

The UKRG's own Catherine Humphreys presented her results on some validation tests she had performed for transporting radiopharmaceuticals at refrigerated temperatures, using type A packages. According to the products' SPCs, certain radiopharmaceuticals must be kept refrigerated after radiolabelling, but this is extremely challenging when they have to be transported to nuclear medicine departments in other hospitals or cities. The Carriage of Dangerous Goods Regulations do not permit the inclusion of items other than the radiopharmaceuticals into Type A containers, making it difficult to keep products cool enough during transport. In addition to this, products are at room temperature when they are prepared, therefore in order to reach a temperature below 8°C

they need to be refrigerated for approximately 45 minutes prior to transport. Catherine recommended that a risk assessment should be conducted for transport arrangements considering the likelihood of external temperatures exceeding 25°C and that realistic control measures should be in place for products which require storage at 2-8°C after preparation.

Ronan Tegala, Clinical Scientist Guy's and St Thomas' Hospital presented his research work undertaken during his Scientific Training Programme (STP) traineeship in Birmingham. His project involved the labelling of nanocolloid (Nanoscan®) with fluorescent dye to form a radiopharmaceutical-fluorescent complex. His conclusions were that the use of a radiolabelled-fluorescent tracer could overcome the shortcomings associated with using dyes and improve the success rate of sentinel lymph node biopsy procedures.

After lunch, the delegates were separated into three groups for the afternoon workshops.

1. Contingency planning for Tc-99m supply: Phil Hillel and Dr Bev Ellis
2. Data integrity risk assessments: Clint Waight
3. Out of specification results (in light of the revised MHRA guidance document)

A brief summary of the workshops was provided by Peter Bartholomew highlighting the more relevant conclusions of each one. To finish, Dr Neil Hartman closed the day thanking the delegates and the companies that supported the event and hoping the workshop was interesting and useful for everyone.

UKRG BOURNVILLE WORKSHOP 2020 (It's in February!)

In a significant break from tradition, the UKRG have moved the Bournville conference from the second Friday in January to **Friday the 7th of February 2020**.



The Beeches at Bournville - arguably the greatest conference venue in the UK

That's right, it's in February! The reason for the change is that January, and also the end of December, can be a very difficult time of year to organise events such as this, and Trusts often have difficulty in processing travel arrangements and invoices that are necessary for delegates to attend. The group felt that moving the date to early in February would potentially suit delegates better, enabling more people to attend and further improving the experience for everyone. There are no immediate plans to change the structure of the workshop, but any ideas or feedback readers may have about this can be communicated to UKRG via your regional UKRG representative.

BREXIT UPDATE

If there's one thing we haven't heard enough about in recent months, it's Brexit! We have held back the publication of this newsletter to bring you a clearer picture of what Brexit might look like, but the best we have is this photograph taken by the Event Horizon telescope...



...that's right, a myocardiocardial perfusion scan!

[Photograph, headline and joke stolen from the Metro and the UKRG Twitter page respectively]

The latest update is that we will leave the EU at some point before the 31st of October 2019. The deal is no closer to being finalised, meaning we do not have a definitive answer to the UK's further participation in the Euratom treaty, or how radioisotopes will be handled by customs. For more up to date information, simply turn on any television at any time, but UKRG newsletter readers are encouraged to follow developments on the BNMS website (link: [BNMS website/ Euratom articles](#)), which updates articles relevant to this issue regularly, as well as the MHRA website, which has a suite of documents relating to contingencies for a No Deal Brexit. Representatives of the UKRG have been involved in direct discussions with the Department of Health, advising on the unique challenges that radiopharmaceuticals present in certain Brexit possibilities, so our concerns are

being raised at the highest tables. Most units will also be in regular contact with product suppliers, particularly regarding the transport of critical items. Discussions are also common in the UK mail-base, linked below, so if you have not already joined in, we encourage you to do so.

www.jiscmail.ac.uk/radiopharmacyuk.

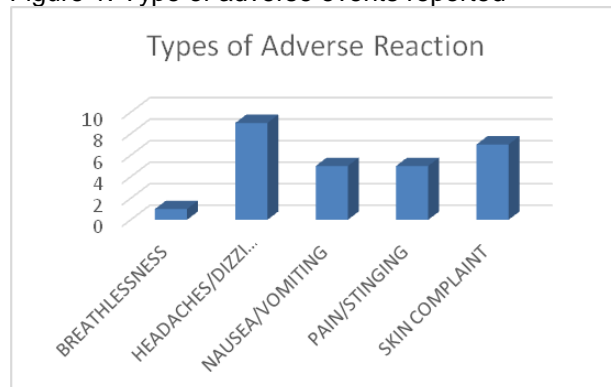
ADVERSE EVENTS AND PRODUCT DEFECTS

Adverse events

There were 19 adverse events reported from radiopharmaceuticals in 2018. Nine of these were of dizziness and headaches, seven were reports of skin complaints, there were five reports of nausea and vomiting, five reports of pain and stinging and one case of breathlessness following injection of Tc99m-macrosalb.

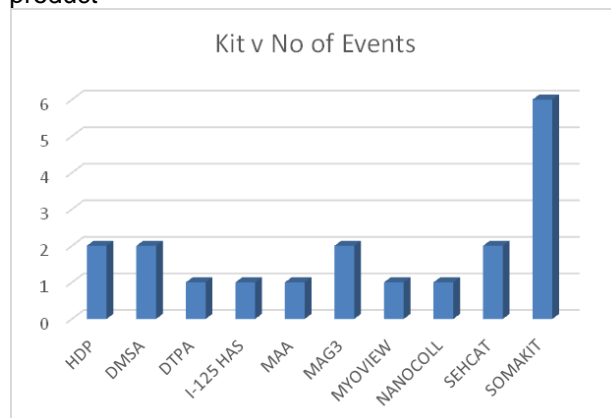
Some patients reported more than one reaction. In two instances, the same adverse event was reported for two separate patients having received doses from the same kit on the same day.

Figure 1: Type of adverse events reported



The highest number of events per product related to Ga68-edotreotide, with three instances of nausea and three instances of stinging upon administration.

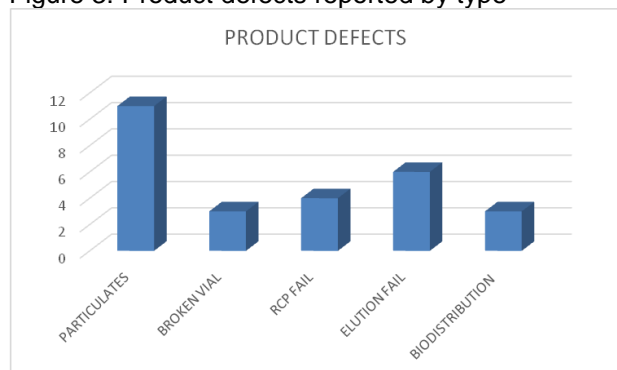
Figure 2: Number of adverse events reported by product



Product Defects

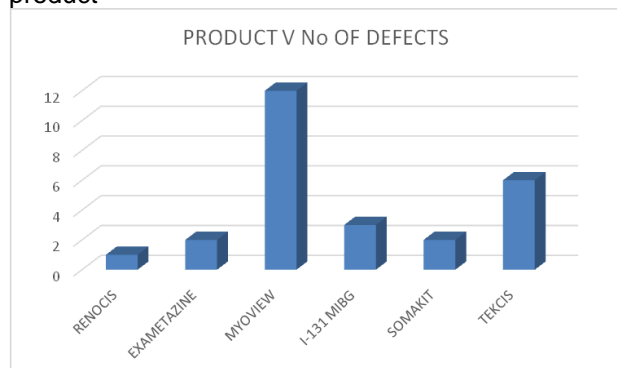
There were 28 product defect reports submitted during 2018. Eleven of these reports relate to particulate contamination from the vial septum. The remaining reports consisted of: 3 instances of broken vials for ¹³¹I MIBG products; 6 reports of failed or incomplete generator elutions; 4 reports of RCP failures and 3 reports of unexpected biodistribution.

Figure 3: Product defects reported by type



The highest number of product defects reported by product was for Tc99m-tetrofosmin due to particulate contamination, which is actively being investigated by the manufacturer.

Figure 4: Number of product defects reported by product



ADVERTISING JOBS IN RADIOPHARMACY

When advertising job vacancies in your unit we encourage you to make use of the Radiopharmacy UK Email Discussion List. This is an excellent way to target your key audience.

If you haven't already joined this discussion group then you still can by following this link: www.jiscmail.ac.uk/radiopharmacyuk. In order to be eligible you need to be employed by the NHS or the academic sector.

In addition to this, the new UKRG Twitter page will be another great way to advertise vacant posts in the future.



@UKRGnews
#radiopharmacyjobs

EMA REVIEW OF NEW MEDICINAL PRODUCTS

The EMA publishes a monthly list of applications for centralised marketing authorisations for human medicines, including radiopharmaceuticals, that are under evaluation by the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP). The list can be found at http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/document_listing/document_listing_000349.jsp&mid=WC0b01ac05805083eb

INDUSTRY NEWS

UKRG Disclaimer: Much of the information in this section is proffered by UKRG Industry colleagues. Inclusion in the Newsletter does not imply endorsement of any particular product by the UKRG. In addition, UKRG is not responsible for any claims made by individual companies.

Supply of macrosalb

Curium have continued to have intermittent and alternating supply issues with Pulmocis and LyoMAA, resulting in the products being sent interchangeably at times, in order to meet demand. Customers should be aware of the differences in the products, in terms of particle numbers and visual appearance, as well as storage conditions following radiolabelling (Pulmocis refrigerated; LyoMAA at room temperature).

Adelphi vials

Supply issues with sterile nitrogen 10ml vials are resolving, but supplies are not back to normal as yet. Many radiopharmacies will still be awaiting backorders being delivered, but Adelphi have some stock available for units that are low in stock. The manufacturing issue has been resolved, but Adelphi are still replenishing their stock deficiencies in order to fulfil back orders.

UPCOMING MEETINGS

British Nuclear Medicine Society Autumn Meeting
9th September 2019, Albert Hall, Nottingham

Website: <https://www.bnms.org.uk/meetings-and-events/autumn-meeting-2019/>

32nd Annual Congress of the European Association of Nuclear Medicine

12th – 16th October 2019, Barcelona

Website: www.eanm.org/congresses-events/future-congress

UKRG Annual Workshop 2020

Friday 7th February 2020, Bournville, UK

Website: www.ukrg.org.uk

FAREWELL TO TOM MURRAY

Another long-serving member of the UKRG, Tom Murray is retiring in 2019 after over 30 years running the busiest radiopharmacy in the UK. Tom was joined by current and former colleagues and friends at the UKRG Committee and Strategic Group meeting in Edinburgh in September 2018, where he was presented with a gift that indulged his other passion in life - single malt scotch whisky!

Tom contributed significantly to the development of Radiopharmacy in his career, publishing several research papers and providing significant support to fellow radiopharmacists in Scotland and the rest of the UK. Tom's position on the UKRG Committee will be taken by his successor, Kay Pollock, who will be the regional representative for the West of Scotland. All of us in the UKRG wish Tom a happy retirement and thank him for his service to the UKRG Committee.

CONGRATULATIONS MARIA PALMER! BNMS NORMAN VEALL MEDAL WINNER 2019

Maria Palmer, Regional Radiopharmacist at the University Hospital Bristol, has been awarded the Norman Veall medal by BNMS in recognition of her contribution to Nuclear Medicine and Radiopharmacy, and here's why...

Being pretty clever, Maria undertook a Master's degree by research into the placental transfer of radiopharmaceuticals and a PhD researching the role of nuclear medicine in osteoarthritis. She has 68 published research papers to her name, and this considerable research experience came in very handy when she became first Deputy Director and then Director of R&D for her Trust.

Maria has been a member of the UKRG for 40 years, spending 8 years of that as Chair, as well as representing Radiopharmacy on the BNMS Council as Chair of the BNMS Radiopharmacy Group and as

BNMS newsletter editor. She has been an extremely active committee member, helping to write countless guidance documents which have greatly benefitted the Radiopharmacy community as a whole, as well as writing chapters for textbooks which many of you will have sitting on your shelves.

In addition to her paid positions with the NHS, since 2007 Maria has been the Director of the UK National Health Service R&D Forum – an organisation which supports clinical research in Health and Social Care in the UK by offering training, running an annual conference and providing professional support and advice. The Forum's input and support is frequently sought by regulatory bodies (e.g. MHRA), government departments (e.g. Department of Health) and the Health Research Authority. Approximately 3500 people look to the Forum for professional support with 600 attending the annual conference.

So Maria's impact on Radiopharmacy and beyond has been considerable, and we are very grateful to her and proud of her. We would like to extend our thanks to her for all she has done to promote and support Radiopharmacy throughout her career and we wish her the very best of luck in the future.



Maria Palmer – arguably the greatest radiopharmacist in the UK

From the Editor

The newsletters are all published on the UKRG website, so if you're interested, please go to www.bnms.org.uk/ukrg/general/newsletters.html where you can read the entire back-catalogue if you wish!

The next meeting of the UKRG Committee will be on 5th July 2019. If readers have any issues they wish to be discussed please raise them with your regional rep on the Committee <http://www.bnms.org.uk/ukrg/general/ukrg-committee-list-2011.html>

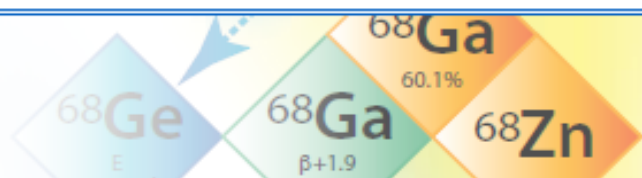
Alternatively, comments on the Newsletter content or on any radiopharmacy issue can be sent direct to the Editor at the address below.

Ga-68 for Beginners

A one day workshop on how to start a GMP Ga-68 manufacturing service

Friday 7th June 2019

09:15 – 09:45 Registration



09:30 – 09:45 **Ge-68/Ga-68 generators: what is on the market, and how to procure it?**

Dr Maggie Cooper
KCL

14:30 – 15:30 **Manufacturing and QC of Ga-68 radiopharmaceuticals: step-by-step**

José Calero
The Christie, Manchester

09:45 – 10:15 **Radiation risk assessments**

Brian Murby,
The Christie, Manchester

15:30 – 15:45

Ge-68 breakthrough determination

David Ashworth
The Christie, Manchester

10:15 – 10:45 **Kits or synthesis modules? A review of both strategies**

José Calero,
The Christie, Manchester

15:45 – 16:15

Staffing needs and a suitable training programme

Pei-San Chan
Royal Free Hospital, London

10:45 – 11:15 **What equipment to buy?**

Dr Jane Sosabowski,
QMUL

16:15 – 16:45

Validation (equipment, process, continuous)

Charlotte Monaghan
Royal Marsden, London

11:15 – 12:00 Coffee break in the Great Hall

12:00 – 12:15 **Ga-68 chemistry and elution technology**

Dr Cinzia Imberti,
University of Warwick

16:45 – 17:05

An overview of documentation (SOPs, worksheets, etc)

Dr Neil Hartman
Swansea

12:15 – 13:00 **Quality control of Ga-68 radiopharmaceuticals**

Dr Maggie Cooper
KCL

17:05 – 17:30

Future Ga-68 radiopharmaceuticals developments

Dr Stefano Boschi
Bologna

13:00 – 14:30 Lunch and visiting exhibitions

U.K.  Radiopharmacy Group

www.ukrg.org.uk

Newsletter 2019 Spring Edition

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