U.K. Radiopharmacy Group

NEWSLETTER

Halloween Edition 2019

In this issue…

Welcome to the (kind of) Summer/ Early Autumn Edition of the UKRG Newsletter!

BOURNVILLE WORKSHOP 2020 (It is now in February)

Please remember the Bournville workshop has moved to **Friday 7th February 2020**.

We hope this change of date will suit delegates better and will be an easier time for Trusts to process invoices and travel arrangements for delegates to attend, rather than try to do this at the end of December!

The UKRG is currently putting together an exciting programme of topics, which will include:

- What every Radiopharmacy should know about transport – preferably before they have an ONR inspection
- An overview of microbial monitoring
- Multidisciplinary teams and dementia, how do they work?
- An audit of radioiodine therapy
- How team culture can improve team performance in Radiopharmacy

…and much more! Similar to previous years, there will be presentations in the morning and group workshops in the afternoon.

The programme and registration details will be available soon on the following link, so keep an eye out for these:

https://ukrg.meeting.org.uk

BREXIT UPDATE

At the time of writing this newsletter, it is still happening, though not until early 2020, but the possibility of leaving the EU without a deal remains. With information changing every day, and quickly becoming out of date, readers are encouraged to keep up to date by following developments on the BNMS website which updates articles on this issue regularly:

https://www.bnms.org.uk/page/BrexitEuratom

Concerns over the potential supply disruption of radionuclides following Brexit have been highlighted in the media over the last few months, including a BBC Newsnight interview on 1st August (links below):

https://www.bbc.co.uk/iplayer/episode/m000779b/newsnight-01082019

https://www.bbc.co.uk/news/education-49153073

Discussions are also common in the UK and EU mail-bases that we have provided links to below, so if you have not already joined one of those, we encourage you to do so.

MONITORING BREXIT SUPPLY ISSUES

The UKRG and BNMS have set up a survey to monitor any supply issues that Radiopharmacies and Nuclear Medicine Departments experience connected to the changes in transportation arrangements due to Brexit. A survey has been set up to capture this data on the BNMS website, which can be found using the link below:

https://www.bnms.org.uk/page/RadionuclideSupplyform

Trusts are currently developing contingency plans to mitigate delays and disruptions to the supply of radiopharmaceuticals in the event of a no-deal Brexit. The Royal College of Radiologists, British Nuclear Medicine Society and UKRG issued a document in March on *Practical advice for Radiopharmacy and nuclear medicine services in*

the event of a no-deal Brexit. This can be found on the following link:

https://www.rcr.ac.uk/sites/default/files/no_deal_brexit_planning_guidance_for_nuclear_medicine_teams_march_2019.pdf'

Communication with suppliers as well as Radiopharmacy and Nuclear Medicine colleagues is of key importance when planning local contingencies to help reduce the likelihood of delays and disruptions.

Ga68 FOR BEGINNERS STUDY DAY EDINBURGH, JUNE 2019

On Friday 7th June in Edinburgh, over 70 delegates and exhibitors attended the UKRG Study Day 'Ga68 for Beginners'. Presenters from the leading UK Ga68 centres came to present their experiences on how to best set up a gallium service in your department. Topics covered included:

- What equipment to buy
- What additional staffing you may require
- Ga68 generators
- Synthesis units vs kits
- Current research and new Ga68 products on the horizon
- Video demonstrations of how to conduct a Ga68 production session (see below)

The meeting was well attended by delegates from all over the UK and Europe, and in particular by the four Scottish centres who are aiming to go live with Ga68 services in Edinburgh, Dundee, Aberdeen and Glasgow in 2020. The Scottish Government has invested in Ga68 in these four centres, as part of the National PET/CT Review, whereby all 14 acute Health Boards in Scotland will contribute financially to these four centres providing Ga68 PET scanning for all patients across Scotland.

UPDATED CHIEF PHARMACISTS' GUIDANCE AND ARSAC EMPLOYER LICENSES

The UKRG Guidance Document *'The Responsibilities of Chief Pharmacists for the Purchase, Receipt, Storage, Supply and Disposal of Radiopharmaceuticals'* is currently being updated. The update will include advice for Chief Pharmacists on the changes to the ARSAC licence arrangements and responsibilities regarding the Employers' licence, which now requires Chief Pharmacists to be named in Question 29 for the responsibility of procurement of all radiopharmaceuticals, regardless of whether the Radiopharmacy is under the line management of the Trust or not. The Chief Pharmacist in all NHS facilities must then sign Section A2 of the form.

In addition to further information on the responsibilities for Chief Pharmacists regarding ARSAC Employer licenses, there is further information on the supply and administration of radiopharmaceuticals for which they should be aware.

INSPECTIONS BY THE OFFICE OF NUCLEAR REGULATION (ONR)

The Society for Radiological Protection held a study day on 'Class 7 Transport for the Small User: Hospitals and Universities' on 19th June 2019.

The study day provided information to organisations that are involved in the transport of radioactive material by road, including radiopharmacies. Jilly Croasdale, UKRG Chair, gave a presentation on '*Preparing for and Receiving a Class 7 ONR Inspection – Radiopharmacy'*. Jilly's presentation covered all aspects of a modern-day ONR inspection, which now require evidence-based risk assessments to be performed for all activities involving the transport of radioactive material. The risk assessments are to be of the equivalent standard to IRR17 assessments, as the ONR inspector will review the IRR17 compliance of your department as it pertains to transport. This is in addition to assessing compliance with the Carriage of Dangerous Good Regulations. The risk assessment should cover radiopharmaceutical manufacture, preparing Type A packages, courier and receipt arrangements. Jilly has kindly agreed to present her experience at the Bournville meeting in February, so make sure you can make it to that.

MHRA's GMDP SYMPOSIUM 2019

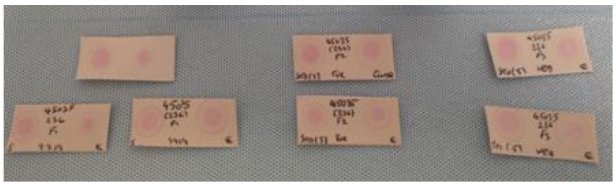
The MHRA are running two symposia in London and one in Glasgow on Good Manufacturing and Distribution Practice. Each symposium is held over two consecutive days, and is ideal for those of you operating under an MHRA "Specials" licence. Each two day event will cover topics such as the Falsified Medicines Directive, Cross-Contamination Control strategies and supplier qualification. The dates for the symposia are detailed in the Upcoming Meetings section of the newsletter, along with the link to register for each event.

"Is it just me?"

This issue's "*Is it just me?*" question comes from Colette in Dundee, who asks:

Is it just me, or has anyone else had issues with Aluminium breakthrough tests on their Tc99m generator recently?

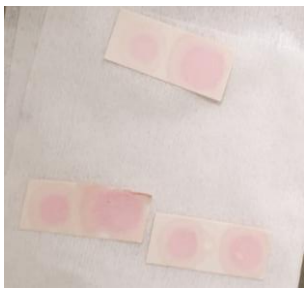
Colette has kindly provided us with photographs of her aluminium breakthrough test results, where the spot intensity does appear to be similar to that obtained from the 5 µg/ml aluminium standard solution.



To answer your question simply:

No, it is not just you!

Zoe from Edinburgh also reported a similar issue in the same week as Colette. Again, these pictures show that the Tc99m eluate has a similar level of aluminium to the 5 µg/ml aluminium standard solution:



It is important to note that if the generator eluate fails to meet the pharmacopoeia specification, which states that it should have an aluminium content of less than 5 µg/ml, then a deviation should be raised and a decision made as to the suitability of that material to be used in production. Clearly, the loss of an entire generator eluate would have a significant impact on your Radiopharmacy's ability to provide a service to patients that day, so any decision to continue to use the eluate must be risk assessed and suitably justified, if deemed to be appropriate. The product that is most likely to be affected by high aluminium levels is Tc99m-tetrofosmin. In circumstances where the aluminium levels are this high, it might be advisable to not prepare this product using that eluate, or ensure it demonstrates suitable stability in radiochemical purity testing before it is released.

So, what caused this to happen in two radiopharmacies that week? Both departments use the same generator supplier and have independently reported this issue to the generator manufacturer. No conclusive explanation has been provided yet, but the manufacturer is still conducting their investigation. Interestingly, both departments experienced a similar phenomenon in March this year, just as preparations for transporting generators by air freight were being conducted. Air freight transport was not used when this second occurrence was reported, but it is interesting to note that both departments are in Scotland and would have been transported by similar methods, therefore it may be something to do with how the generators are handled during transport.

Once the manufacturer has concluded their investigations, we might be able to provide readers with further information on this topic. This case is, however, a good reminder of the importance of conducting the aluminium breakthrough test on the eluate of new Tc99m generators.

If you would like to ask another "*Is it just me?*" question, email the UKRG Newsletter editor at clint.waight@nhs.net, with the title "Is it just me?" and I'll anonymously ask the question here for you.

FEEDBACK FROM THE MHRA

Update from recent inspections

The MHRA regularly provide the UKRG with an update on common findings they have reported when performing GMP inspections of UK Radiopharmacies. The three most commonly found areas of deficiency are

- Lack of appropriately trained personnel
- Quality Management Systems
- Out of date, inadequate facilities

Deficiencies reported on MHRA GMP inspections will also be referenced against the relevant clauses of EC GMP (EudraLex - Volume 4 – Good Manufacturing Practice (GMP) Guidelines.

The MHRA is developing a searchable database for deficiencies found against specific EC GMP clauses from GMP inspections. This database would enable MS Licence holders to have an up to date view of inspection findings. This may be useful to Units for reviewing and maintaining GMP compliance.

If Units are using 3rd party audits (3PA) for their supplier approval process, the following caveats should be followed:

- The 3PA should be critically assessed and the scope of the audit should be appropriate
- Audits should be referenced to the relevant clauses of EC GMP (if audits are based on American systems, they may not be referenced to EC GMP)
- Evidence should be provided of auditor credentials. (This also includes ensuring that they have the relevant expertise of the area being audited)

UKRG TWITTER ACCOUNT

As previously mentioned the UKRG now has its own Twitter account. We will continue to post more up to date news and events which occur more frequently than the newsletter is published and this may be a great way to advertise vacant posts.

Just a reminder that the handle is @UKRGNews, so look us up and give us a follow!

#radiopharmacychat #UKRG #giveusafollow

NEW LOOK UKRG WEBSITE

You may be aware that the BNMS website has been revamped. As the UKRG website is also hosted with the BNMS website, we also have a fancy new look for our website. The URL www.ukrg.org.uk will still take you to the website and access can also be found on the BNMS website landing page. All the essential content from the old site should have been transferred over to the new website. However if you notice that some information is missing, please contact bev.ellis@mft.nhs.uk

RADIOPHARMACY UK AND RADIOPHARMACY EUROPE EMAIL DISCUSSION LIST

A good number of professionals and colleagues have joined the conversations on the Radiopharmacy UK Email Discussion List.

If you belong to the UK Radiopharmacy community in the NHS or the academic sector you can still join the discussion list by following the link: www.jiscmail.ac.uk/radiopharmacyuk.

As mentioned in the last newsletter, a European-wide discussion group has also been established where anyone in Radiopharmacy (academic or hospital) in Europe can ask to join by sending an email to the discussion group administrator at the following address: Neil.Hartman@wales.nhs.uk

The email should include your first name, surname, email address, institution address and a brief sentence on which aspect of hospital or academic Radiopharmacy you are involved in. All communications will be strictly limited to the group and won't be able to be searched from any other source. The group email address is: europeradiopharmacy@jiscmail.ac.uk but this is only accessible once you have been added to the subscription list.

Come and join in today! We all can contribute to find answers to frequent problems in our daily routine, share best practice and keep up to date with new developments in our Radiopharmacy community.

QA/ TECHNICAL SERVICES SYMPOSIUM

The NHS Pharmaceutical Quality Assurance and Technical Services Symposium will be held on 27th and 28th November 2019 in Bristol Marriott Hotel City Centre. Topics covered will include

- MHRA deficiencies found in 'Specials' Units
- National Aseptics Review – phase 2 update
- Human Microbiome – update on what is known and potential impacts for cleanroom management

Further information and registration details can be obtained at:

https://pasg.nhs.uk/upcoming-events

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 this URL:
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.

There are on-going supply problems with **Nanocoll** (GE Healthcare®) and **Choledíam** (MPharma).

There are alternative licensed Tc99m-nanocolloid products available, however they are licensed for a far narrower spectrum of indications than Nanocoll. Therefore, Radiopharmacies and NM departments are having to use products for off-licence indications until the supply issue has fully resolved. There are no licensed alternatives for Choledíam.

UPCOMING MEETINGS

NHS Pharmaceutical Quality Assurance and Technical Services Symposium, Bristol, 27 & 28th November 2019
Website: https://pasg.nhs.uk/upcoming-events

UKRG Annual Workshop 2020
Friday 7th February 2019, Bournville, UK
Website: www.ukrg.org.uk

20th European Symposium on Radiopharmacy and Radiopharmaceuticals, Verona, 7-10th May 2020
Website: https://www.esrr.info/

British Nuclear Medicine Society Spring Meeting, Liverpool 18-20th May 2020
Website:
https://www.bnms.org.uk/page/BNMSMeetingSpring2020

MHRA GMDP Symposium 2019
https://mhragmdp.co.uk/home

London: 11th&12th or 13th&14th November 2019
Novotel London West Hotel, Hammersmith

Glasgow: 26th&27th November 2019
Glasgow Hilton Hotel

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!

Future meetings of the UKRG Committee will be on the 5th & 6th February 2020. If readers have any issues they wish to be discussed please raise them with your regional rep on the Committee
https://www.bnms.org.uk/page/Committee

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

www.ukrg.org.uk

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