

**REVIEW OF THE 2017 UKRG ANNUAL  
WORKSHOP IN BOURNVILLE**

*The editor would like to thank Dr Tom Murray for providing this report on the Bournville workshop.*

Dr Neil Hartman provided a sterling effort to bring the day together, which saw UKRG annual workshop being held on Wednesday 11<sup>th</sup> January. Movement from the normal Friday still attracted a good turnout of delegates and exhibitors. Working in his capacity as chairman Neil introduced each speaker in turn.

First up was UKRG's very own Dr Maggie Cooper, providing a presentation entitled "Current status of <sup>68</sup>Ga-tracers: technical". Topics covered included the range of available generators, requirements and siting, type of workstation, chemical synthesis units, range of available tracers and the quality control tests involved. Maggie pointed out that this service should include appraisal of staffing and capacity issues as each agent manufactured involved approximately 6 hours of work.

The next presentation was "Current status of <sup>68</sup>Ga tracers: Clinical" provided by Dr Luigi Aloj from Addenbrooke's Hospital. He detailed agents that were established as well as those that were up and coming and the future direction, including therapy with other radionuclides. PET agents will provide accuracy in initial staging of disease and will find a place in response monitoring and guiding treatment planning.

Tracia-Gay Kennedy-Dixon a pharmacist on an IAEA fellowship was next to present, giving a "Summary of radiopharmaceutical adverse events" based on the UKRG website database. Dermatological side effects were the most common at 30%, while interestingly female patients were more likely to report their reactions (66%) than men.

A break for coffee and exhibition followed. Taking time out from her busy inspection schedule Saima Ahmad from the MHRA provided a talk on "What an MHRA Inspector looks for in Radiopharmacy". The inspection process is comprised of three

components namely pre-inspection, inspection and the post-inspection process, with a formal risk rating being applied to each manufacturer. Radiopharmacy is regarded as high risk due to the preparation of sterile injections and the absence of end product testing prior to use. Emphasis should be placed on a well-managed Pharmaceutical Quality System.

We are grateful to Jilly Croasdale who replaced our expected presenter at short notice to give the "UKRG Guidance for Key Performance Indicators (KPI's) in Radiopharmacy", a guidance document that will be published on the UKRG website in the not too distant future. KPI's can be seen as providing information about the success or quality improvement of a service.

The sixth presentation of the morning was a joint one from speakers from Industry discussing "future supplies of <sup>99</sup>Mo and <sup>99m</sup>Tc". Mathilde Figon (GE) and Mart Jan Blauwhoff (Mallinckrodt) presented information on the future supplies of <sup>99</sup>Mo generators from the various reactors worldwide. Although Chalk River and Saclay, are now no longer operating, other reactors are ramping up with irradiations and two further reactors in Poland and Germany are helping to supplement supplies. The move to low enriched uranium targets will provide a number of challenges including a likely cost implication. As an alternative, Ron Barrack (Alliance Medical) presented his company's plan to supply the UK with "Cyclotron-produced <sup>99m</sup>Tc". Two existing Cyclotron sites at Dinnington and Guildford will have their cyclotron upgraded to provide the higher energy required to irradiate the molybdenum-100 target to create Tc-99m. Alliance should have this source of material available some time in 2019. Likewise, GE are looking at an alternative to reactor produced molybdenum, with SHINE technology based on particle accelerator technology, in association with low enriched uranium targets.

Lastly, Dr Bill Thomson from Birmingham looked at the optimization of activities and costs of molybdenum generators using a spreadsheet he has developed. This tool which is available from Bill on request is a welcome addition to the strategies at our disposal in tackling scarcities.

Just before Lunch and the Exhibition the delegates were separated into four groups for the afternoon Workshop as follows:

1. Using the UKRG capacity plan: Clint Waight
2. RCP testing: Maggie Cooper
3. Implementing QAAPS 5<sup>th</sup> Edition -new standards for aseptic units: Alison Beaney.
4. What happened to the old products? - Tom Murray

Evaluation forms have been returned and show all talks and workshops were received extremely favourably by the delegates.

We are grateful to Neil Hartman and the UKRG for organising yet another thought-provoking and enjoyable day on all matters radiopharmaceutical.

### **BOURNVILLE WORKSHOP 2018 (It's back to a Friday)**

UKRG is pleased to announce that the 2018 Annual Workshop will take place at The Beeches Management Centre, Bournville, on **Friday 12<sup>th</sup> January 2018**.

Full details of the Workshop programme will be circulated later in the year

The UKRG would welcome suggestions for topics for the workshop. Please email any suggestions to [Neil.Hartman@bartshealth.nhs.uk](mailto:Neil.Hartman@bartshealth.nhs.uk)

### **RADIOPHARMACY UK EMAIL DISCUSSION LIST LAUNCH**

UKRG is pleased to announce the launch of the Radiopharmacy UK Email Discussion List hosted on the JISCMail website.

This discussion list is for the UK Radiopharmacy community in the NHS and Academic sectors.

You can subscribe to this list using the following link [www.jiscmail.ac.uk/radiopharmacyuk](http://www.jiscmail.ac.uk/radiopharmacyuk). This mail-base will provide a useful platform for Radiopharmacy staff to share practice, help each other out, and get answers to questions like "is it just me, or has anyone else had...?"

It will also be a mechanism for publication of the UKRG Newsletter, improving the speed of circulation, so sign up now!  
(Go on, just click the link, it takes about 20 seconds, then read the rest of the newsletter later).

### ***"Is it just me?"***

It's been a while since the last newsletter, but it is important that we resolve the issues that readers are having out there. Last year, in the Q3 newsletter, one of our readers asked:

#### ***"Is it just me, or is anyone else experiencing sporadic low elution yields from their Tc-99m generators?"***

*"We went through a period where we experienced significantly reduced elution yields from around the third/fourth elution onwards on a cycle of roughly once every four weeks. We did consider the "alcohol poisoning" chestnut but we still had the problem when we were extra vigilant and repeated flushing elutions did not return yields to normal. There was no correlation to operators working with the generators."*

Thank you to all of those who kindly responded to this. We may not always solve the problem, or even suggest things you haven't thought of, but the main thing is, you know it isn't just you!

Response:

Low yields in my experience happen for two reasons.

(1) **Wet Bed Phenomenon** – where either an operator has not allowed enough time for the column to be dried after the saline has been pulled through, or the elution vial vacuum has been compromised. It is important to wait for all the bubbles to stop before removing the evacuated vial from the elution needle.

(2) **Elution volume:** generators above a certain size from some manufacturers require a larger elution volume. Using small elution volumes, such as 5ml, in some generators may not be sufficient to obtain all of the Tc-99m generated.

For this month's "Is it just me?" I'm going to ask a question that a few others, including myself (so it isn't just me, or them) have recently pondered...

#### ***"Is it just me, or has anyone had reports of lung perfusion scans using macroaggregated albumin (MAA) with the appearance of unexplained high free pertechnetate?"***

In my experience, we have had scans showing evidence of significantly higher free pertechnetate, than the 2% or so that has been measured using radiochemical purity tests, even when the same vial is tested.

If you have an answer, email me at [clint.waight@nhs.net](mailto:clint.waight@nhs.net), with the title "Is it just me?"

## UKRG ERROR REPORTING SCHEME - REMINDER

Please do continue to send in error reports to our on-line system as the results can be analysed to provide valuable information on future training requirements. A summary of the error reports will be published in the next newsletter.

If you can't remember where to find the report forms, just click on the link below:

[http://www.bnms.org.uk/images/stories/UKRG/UKRG\\_Error\\_Reporting\\_form.pdf](http://www.bnms.org.uk/images/stories/UKRG/UKRG_Error_Reporting_form.pdf)

## UKRG RADIOPHARMACY AUDIT

The UKRG Radiopharmacy [Audit](#) has been updated and is available on the UKRG website as a pdf and word document. This document may be useful for undertaking routine self-inspection to comply with EU GMP requirements or for carrying out external audits.

## UKRG GUIDANCE NOTES UPDATE

The [Quality Assurance of Radiopharmaceuticals](#) document has been updated (November 2016) to include a Critical Impact Assessment.

There is a new Guidance Note being developed on Key Performance Indicators (KPI's) in Radiopharmacy. Performance indicators may be used to underpin the continuous improvement principles required by EU GMP.

There are some Guidance Notes currently under review and these include

1. Capacity planning toolkit
2. The Responsibilities of Chief Pharmacists for the Purchase, Receipt, Storage, Supply and Disposal of Radiopharmaceuticals (this will supersede the Guidance Note 'Responsibilities of Chief Pharmacists for the purchase and supply of radiopharmaceuticals').

These new and updated documents will be issued later in the year.

If anyone wants the capacity plan tool before then, email the Editor, he doesn't mind at all!

## QUALITY ASSURANCE OF ASEPTIC PREPARATION SERVICES 5<sup>TH</sup> EDITION UPDATE

The Quality Assurance of Aseptic Preparation Services (5<sup>th</sup> Edition) can now be purchased as a hard-copy book from the [Pharmaceutical Press](#).

An [Aide Memoire](#) audit record sheet has been produced for EL auditors and may also be useful for Units undertaking a local gap analysis for compliance with the standards

## SCIENTIST TRAINING PROGRAMME (STP) IN CLINICAL PHARMACEUTICAL SCIENCE

The first cohort (2013 intake) of eight Clinical Pharmaceutical Science (CPS) STP trainees all graduated with a MSc and successfully completed the Objective Structured Final Assessments (OSFAs). All these trainees have found suitable jobs in the pharmaceutical technical specialties, including four posts in Radiopharmacy.

There have been a couple of articles published in the *Pharmaceutical Journal* on careers in the pharmaceutical technical specialties which feature the work of the CPS STP trainees. The articles can be found using the following links:

<http://www.pharmaceutical-journal.com/opinion/correspondence/a-solution-to-the-skill-gap-in-pharmacy-technical-services/20201447.article>

<http://www.pharmaceutical-journal.com/careers/career-feature/pharmacy-technical-services-what-it-involves-and-who-can-work-in-this-area/20201392.article>

For the 2017 intake; six direct entry posts and one in-service post have been approved by Health Education England.

## KING'S COLLEGE LONDON RADIOPHARMACY ADVANCED COURSE

The four-day lecture and practical Radiopharmacy Advanced course took place at St Thomas' Campus, London from Tuesday 28<sup>th</sup> March to

Friday 31<sup>st</sup> March 2017, and will be held each year as part of the PTQA and STP courses through Manchester University. However, the course is open to all Radiopharmacy staff as a stand-alone course, and as an extension to the long-running and very successful King's Course (or Easter Course, for those who remember), which is now known as "An Introduction to Radiopharmacy."

Topics include radiopharmaceutical chemistry, biologicals (proteins, peptides, and cells), positron emission tomography (PET), molecular radiotherapy, and selected clinical topics.

For more information please visit:

<http://tinyurl.com/kingsradiopharmacyadv2017>

## BNMS ANNUAL SPRING MEETING 2017

The BNMS Annual Spring Meeting will be held from Saturday 20<sup>th</sup> May to Monday 22<sup>nd</sup> May 2017 at the International Conference Centre, Birmingham

There will be two Radiopharmacy sessions on Sunday 21<sup>st</sup> May including invited reviews and proffered papers.

## REGULATORY ISSUES

### MHRA Inspectors

Saima Ahmad has re-joined the MHRA Inspectorate and is now the Technical Lead Inspector for 'Specials' which includes Radiopharmacy. Ian Harwood is the deputy lead.

### Recent Inspection Issues

MHRA inspectors have observed a general decline in compliance with standards in recent years, with a summary of the commonly found issues described below:

1. *Quality Management System (QMS)*  
Insufficient investigation and management of deviations, complaints, out of specification results and product recalls. Recurrence of the same issue, indicating that CAPAs are ineffective.
2. *Personnel*  
Lack of GMP knowledge, experience and capability of key personnel named on the licence. Staff being reactive, rather than proactively planning and developing the quality system and service

3. *Validation and Change Control*  
Change control not always used or not used in a useful way. Appropriate validation is not always performed
4. *Documentation*  
Often inadequate such as only brief records made for serious quality issues
5. *Production*  
Poor aseptic techniques observed by inspectors
6. *Outsourced Activities*  
Lack of review of Technical Agreements and control of outsourced tasks
7. *Manufacturing Licence Holder Responsibilities*  
Capacity planning is not always employed to ensure that there are sufficient resources to fulfil GMP requirements. Units are not always keeping the MHRA updated of key changes or serious events by submitting compliance reports. Deficiencies found during inspection are not always resolved within the agreed time scale.

The MHRA have also published their common inspection deficiencies from 2015. This can be found at the following URL:

<https://www.gov.uk/government/statistics/good-manufacturing-practice-inspection-deficiencies>

## 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](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/document_listing/document_listing_000349.jsp&mid=WC0b01ac05805083eb)

Currently <sup>18</sup>F-Fluciclovine and Lutetium (<sup>177</sup>Lu) dotatate are under evaluation.

## 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 individual companies.

### **IBA Molecular Acquisition of Mallinckrodt Nuclear Imaging**

On January 27<sup>th</sup> 2017, Mallinckrodt completed the sale of its Nuclear Medicine Imaging business to IBA Molecular following the receipt of regulatory approvals. The merger will result in a new company name and brand. The detail of the integration of the two businesses is not yet known. In the meantime, it will be 'business as usual' and the two companies will continue to engage with customers as IBA molecular and Mallinckrodt Nuclear Imaging.

### **Alliance Medical**

Alliance Medical has been acquired by Life Healthcare, a private hospital operator in South Africa. Further information can be found using the following link

<https://www.alliancemedical.co.uk/news/alliance-medical-acquired-by-life-healthcare>

### **Updated SPC for IEL MAG3**

IEL has revised the Summary of Product Characteristics (SPC) for non-boil MAG3. The shelf-life of the radiolabelled product is 8h (when stored below 25°C). The MAG3 (0.2 mg mertiatide) can now be radiolabelled with a maximum of 4 GBq in 8 ml (total volume after labeling is 10 ml including buffer solution). Please refer to the revised SPC (sections 6.3 and 12) for further information

### **Marketing Authorization granted for SomaKit TOC™ (Advanced Accelerator Applications)**

The European Commission has granted a marketing authorization for SomaKit TOC™ valid throughout the European Union. SomaKit TOC™ is for the preparation of gallium (Ga-68) edotreotide solution for PET imaging of somatostatin receptor overexpression. The kit will be available from IEL. Further information may be found at the following link:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004140/human\\_med\\_002038.jsp&mid=WC0b01ac058001d124](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004140/human_med_002038.jsp&mid=WC0b01ac058001d124)

## **UPCOMING MEETINGS**

### **12<sup>th</sup> European Molecular Imaging Meeting**

5-7 April 2017, Cologne, Germany

Website: <http://www.e-smi.eu/index.php?id=2652>

### **12<sup>th</sup> Congress of the World Federation of Nuclear Medicine and Biology**

20-24 April 2017, Melbourne, Australia

Website: [http://wfnmb2018.com/wp-content/uploads/WFNMB2018\\_Sponsorship\\_Prospectus.pdf](http://wfnmb2018.com/wp-content/uploads/WFNMB2018_Sponsorship_Prospectus.pdf)

### **British Nuclear Medicine Society Annual Spring Meeting**

20-22 May 2017, ICC, Birmingham

### **Society of Nuclear Medicine and Molecular Imaging Annual Meeting**

10-14 June 2017, Denver, USA

Website: <http://www.snmim.org/am2017>

### **30<sup>th</sup> Annual Congress of the European Association of Nuclear Medicine Congress**

21<sup>st</sup>-25<sup>th</sup> October 2017, Vienna

Website: <http://www.eanm.org/>

## ***From the Editor***

As editor of the UKRG newsletter, I often receive requests from readers to be on the newsletter mailing list. I should point out that there is no mailing list for the newsletter as such, other than through your UKRG regional representative. However, 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](http://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 27<sup>th</sup> April 2017. If readers have any issues they wish to be discussed please raise them with your regional rep on the Committee (full details at this URL):

<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.



[www.ukrg.org.uk](http://www.ukrg.org.uk)

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