



**SPORICIDALS AND THE
RADIOPHARMACY EXEMPTION**

The MHRA recently updated its Guidance for Specials Manufacturers ("The Q&A Document"), to include the use of sporicidal agents in the transfer of materials into a Grade A workstation. This recommendation came from lessons learned in a recent incident involving the contamination of neonatal parenteral nutrition bags with *Bacillus cereus*, a spore-forming microbe. The MHRA guidance specifically identifies radiopharmacies as being exempt from the requirement to use a sporicidal agent, based on the risk that oxidising agents, such as hydrogen peroxide, pose to the quality of radiopharmaceuticals.

Regional QA centres, [and the newsletter editor] have had several enquiries about the exemption for Radiopharmacy using sporicidal agents, so it was decided to provide a little more information for radiopharmacies in this month's newsletter. The evidence that this exemption is based on comes from the publication of an abstract, demonstrating the detrimental effect that sporicidal agents, such as hydrogen peroxide, have on the radiochemical purity of Tc99m-radiopharmaceuticals.¹ The mechanism for affecting the quality of the product was oxidation of stannous chloride, a reducing agent present in most routinely used radiopharmaceutical kits. This known level of risk to the quality of radiopharmaceuticals, presently outweighs the potential risks associated with not using sporicides in current Radiopharmacy practice.

Although radiopharmacies are not being asked to adopt sporicidal agents at present, it may be expected that this decision is risk assessed, and the above information might be useful in formulating such a risk assessment in your department.

Reference:

1. Stringer RE, Schroeder NE, Maltby PJ. MAG3 failure is due to inadvertent oxidant contamination. *Nuclear Medicine Communications*. 1997; 18: 294.

**BOURNVILLE 2016
UKRG ANNUAL WORKSHOP**

The UKRG Annual Workshop will once again take place at The Beeches Management Centre, Bournville, on **Friday 15th January 2016**. For those who have not already received a booking form for this event, there is a copy attached to this newsletter, as well as full details of the Workshop programme.

All returned registration forms should be submitted to the Workshop Organiser, Adrian Hall, at the following address:

Dr Adrian Hall
Radiopharmacy
The Royal Marsden NHS Foundation Trust
Downs Rd, Sutton
Surrey SM2 5PT

Adrian.hall@rmh.nhs.uk

UKRG REGIONAL REPRESENTATIVES

Just a reminder to everyone about the structure of the UKRG and how each Radiopharmacy is represented across the United Kingdom. The UKRG Committee is made up of regional representatives, so that each Radiopharmacy should be receiving UKRG communications through their respective regional committee member. If you are not sure who your regional committee member is, the full list is on the UKRG website at:

<http://www.bnms.org.uk/ukrg/general/ukrg-committee-list-2011.html>

ARSAC NEWSLETTERS

Two recent ARSAC newsletters may be of interest.

- How and when to submit research applications.
<https://www.gov.uk/guidance/how-and-when-to-submit-research-applications-to-arsac>
- Adding 18F radiopharmaceuticals to a diagnostic licence.
<https://www.gov.uk/guidance/adding-18f-labelled-radiopharmaceuticals-to-a-diagnostic-arsac-certificate>

CERT WEBSITE

CERT is a collaboration between three organisations with an interest in molecular radiotherapy: Cancer Research UK (CR-UK); Experimental Cancer Medicine Centres (ECMC) and UK Radiopharmacy Group Taskforce.

. The purpose of this resource is to provide guidance and advice related to the set-up of clinical trials using radiopharmaceutical Investigational Medicinal Products (rIMPs). It includes:

- A detailed step by step overview of the process from building the initial study concept to submitting your Clinical Trials Authorisation (CTA) application to the MHRA
- A roadmap highlighting each step in the above process
- An IMPD advice document which has been written specifically for radiopharmaceuticals
- Links to useful websites/groups and contact details to experts who are willing to provide help with many of the aspects involved in setting up these studies

The website resides behind a password protected area by clicking on the "Members Only" section at the following url:

<http://www.ecmcnetwork.org.uk/network-groups/cert-group/>

If you are interested in gaining access to the members only section then please contact James

Ritchie at James.Ritchie@cancer.org.uk who will send you a username and password.

ERROR REPORTING

The on-line Error Reporting Form is available on the UKRG website. The UKRG would like to encourage centres to use this scheme as the results can be analysed to provide valuable information on future training requirements.

A summary of results from a pilot study was published in the last newsletter, and will be updated when reports become available, or at least annually.

KEY PERFORMANCE INDICATORS

A UKRG working group is developing a Guidance Document on Key Performance Indicators (KPI's) for Radiopharmacy Services and would be interested to know what KPI's (if any) departments are currently using. If you are happy to share these please email davidgraham1@nhs.net

REGULATORY ISSUES

As stated in the previous newsletter, the MHRA want to see evidence that licensed units are regularly checking for GMP updates. If you haven't already done so, it is a good idea to sign up for MHRA email alerts. Simply follow the link below and choose what you want to be kept up to date with:

<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/email-signup>

Update on EU GMP

In addition to keeping up to date with MHRA guidance, it is a good idea to routinely check for updates on the EudraLex website at this URL:
http://ec.europa.eu/health/documents/eudralex/vol-4/index_en.htm

[Annex 15](#) on **Qualification and Validation** has been revised went into operation on the 1st of October 2015.

[Annex 16](#) on **Certification by a Qualified Person and Batch Release** has been revised. The

deadline for coming into practice is the 16th of April 2016.

[Annex 17](#) on Parametric Release is being revised. A consultation was launched on the 15th of September 2015 on a [draft revised version](#) of Annex 17. The consultation closes on the 11th of December 2015.



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 individual companies.

 **All I want for Christmas is a reliable, sustainable source of Mo99 for preparation of Tc99m radiopharmaceuticals for the foreseeable future.** 

SHINE Medical Technologies and GE Healthcare may have read your letter to Santa, as they announced that they have successfully obtained Tc99m from a GE Healthcare Drytec generator that was manufactured using molybdenum-99 prepared by SHINE. The test provides encouraging evidence that SHINE is able to successfully produce molybdenum-99 that is suitable for use in GE Drytec generators, adding another process into the existing, and soon to be temporarily diminishing, molybdenum-99 supply chain.

Despite this being a positive step towards securing a reliable supply of molybdenum-99, we might not see commercial production of SHINE-produced Mo99 until 2019, pending routine regulatory procedures. The test did result in the successful preparation of several Tc99m-radiopharmaceutical kits, which is an encouraging sign.

Mallinckrodt improves labelling of Technescan MAG3 kit

As mentioned in the previous edition of the newsletter, Mallinckrodt has officially announced the changes to the SPC for Technescan MAG3, which now has a maximum activity that can be added to the vial is 2960 MBq in a volume of 10 ml. The shelf-life of the radiolabelled product has increased from 4 hours to 8 hours (when stored below 25°C), and the SPC now lists that heating can be performed in a heating block, as well as the traditional water bath. Please refer to the revised SPC (sections 6.3 and 6.6.1) for further information.

GE Web Ordering

GE Healthcare's new Web Ordering system is now live and they are inviting customers to register to utilize the benefits it has to offer. This tool allows you to:

- Order products at your convenience 24 hours a day
- View your order history
- Search through your available product range
- Save items to your favourites
- View current order status
- Repeat your past orders with ease
- View your PO spending
- Check what orders have been placed by 'procurement' if you do not place orders directly

To register, please go to ci.gehealthcare.com If you have any questions about Web Ordering, or need helping registering, please contact Customer Service on 0800 558822 our your local Key account Manager

CLINICAL PHARMACY CONGRESS 2016

For the 2016 Clinical Pharmacy Congress the UKRG is working with the organisers to include sessions on radiopharmaceuticals in clinical practice complementing a broad programme of clinical and technical pharmacy. Apart from these specialist sessions much of the programme content will be of interest to people working in Radiopharmacy. It is worth checking out the programme here <http://www.pharmacycongress.co.uk/Content/Delegate-Info/3/>

Each UK hospital can access 10 free places for registered pharmacists and technicians and the deadline for using the free access codes is 29th January 2016 (further details in the FAQ section at the above website).

BNMS ANNUAL SPRING MEETING 2016

The BNMS Annual Spring Meeting will be held from Sunday 17th April to Tuesday 19th April 2016 at the International Conference Centre, Birmingham

The UKRG would like to encourage people to submit abstracts to support the Radiopharmacy sessions. The deadline for submitting abstracts is likely to be early January 2016.

UPCOMING MEETINGS

2016

UKRG Annual Workshop 2016

15 January, Bournville, UK

Website: www.ukrg.org.uk

11th European Molecular Imaging Meeting

8-10 March, Utrecht, Netherlands

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

The Clinical Pharmacy Congress*

The future of Clinical Pharmacy

22-23 April, 2016

ExCel London, Royal Victoria Doc 1 Western Gateway, London

*In 2016, the Clinical Pharmacy Congress will be working closely with UKRG and will include lectures on radiopharmaceuticals in clinical practice. More details on these lectures will follow.

BNMS Annual Spring Meeting 2016 (Celebrating 50 years)

17-19 April, 2016, ICC, Birmingham

SNMMI 2016 Annual Meeting

11-15 June, 2016 San Diego, USA

Website: [SNMMI Annual Meeting 2016](http://www.snmmi.org/annual-meeting-2016)

From the Editor

My thanks to all who contributed items for inclusion in this issue of the Newsletter, in particular to Maria Palmer for editing this issue.

The next meetings of the UKRG Committee and Strategic Group will be in Bournville 13th and 14th of January, followed by the annual workshop on the 15th of January. 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

Newsletter 2015-Summer Edition

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UK RADIOPHARMACY GROUP WORKSHOP 2016

Continuing Professional Development in Radiopharmacy

To be held on 15th January 2016 at

The Beeches Management Centre, Bournville, Birmingham

FINAL PROGRAMME

08.45 – 09.15 Registration and Coffee

09.15 – 09.45 Clint Waight, Principal Pharmacist, Royal Infirmary of Edinburgh
“⁹⁰Y SIR-Spheres”

09.45 – 10.15 Maggie Cooper, Chief Radiopharmacist, Royal Liverpool and Broadgreen University Hospital
“Nanocolloid kits – are they all the same?”

10.15 – 10.30 Kimberley Wright, STP trainee, University Hospitals Birmingham NHS Foundation Trust
“A personal perspective of the STP training programme in Clinical Pharmaceutical Science”

10.30 – 11.15 Coffee and exhibition

11.15 – 11.30 Scott Edmonds, STP Trainee, Guy’s and St. Thomas’ NHS Foundation Trust
“Cell labelling with Zr-89”

11.30 – 12.00 Dr. Alison Beaney, Quality Assurance Specialist, North-East England
“New standards from “Quality Assurance of Aseptic Preparation Services, edition 5””

12.00 – 12.30 Dr Peter Jarritt, Project Manager, iCEPSS Programme, Academy for Healthcare Science
“Accreditation for radiopharmacy”

12.30 – 14.00 Lunch & Exhibition

Afternoon Syndicate work

14.00 – 15.30 Workshops - Parallel Syndicate Sessions

Group 1 How to perform risk assessments / impact assessments on deviations
Jilly Croasdale, Tom Murray

Group 2 Methods for detecting radioactive spills / contamination in radiopharmacy and associated risk assessments
Phil Hillel, Colette Burns

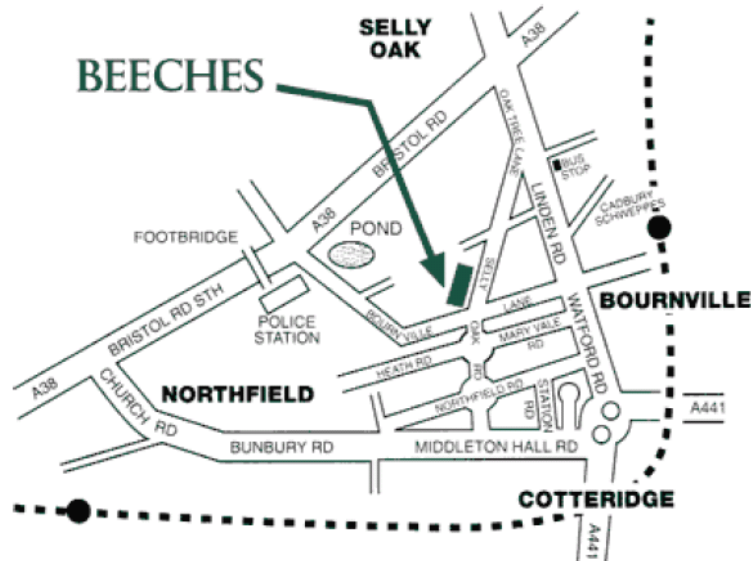
Group 3 Trending in radiopharmacy
Beverley Ellis, Maggie Cooper

15.30 – 16:00 Feedback from syndicate sessions

16.00 – 16.10 Summing up

16:15 Depart

THE BEECHES – DIRECTIONS



For Door To Door Directions & Traffic Information Use This Link:
<http://www.multimap.com>

By Rail

To BIRMINGHAM NEW STREET, then taxi (20 minutes).
To BIRMINGHAM NEW STREET, then change for local train to BOURNVILLE followed by a half-mile walk.
Call 0845 748 4950 for more detailed information and times

Directions from the M6

From Junction 6 follow signs to BIRMINGHAM CITY CENTRE - A38(M). Keep in the right-hand lane onto the flyover.
Stay in the right hand lane and go under three underpasses.
Continue on the A38 straight on through SELLY OAK.
After half a mile at the foot of a hill there is a pedestrian bridge, immediately before turn left into BOURNVILLE LANE, a Police Station is on the corner.
Approximately half a mile up the hill take a left turn into SELLY OAK ROAD.
The Beeches is 100 yards down on the left hand side.

Directions from the M42

From Junction 2 turn onto A441 TO BIRMINGHAM.
Continue over next four islands (becomes Pershore Road South).
At the next island (you are now in Cotteridge with shops on your left) turn left into MIDDLETON HALL ROAD and you will immediately cross a pedestrian crossing.
Take the third turn on the right into SELLY OAK ROAD (just before a set of pedestrian lights).
Continue over two roundabouts and one crossroads.
The Beeches will be 100 yards down on the left hand side.

The Beeches Training Centre
Selly Oak Road, Bournville, Birmingham, B30 1LS
Tel: 0121 433 3311
Fax: 0121 459 1509
Email: beeches@chartridge.co.uk

UK RADIOPHARMACY GROUP WORKSHOP 2016
Continuing Professional Development in Radiopharmacy To
be held on 15th January 2016 at
The Beeches Management Centre, Bournville, Birmingham

BOOKING FORM

Name (BLOCK CAPITALS PLEASE)			
Organisation			
Address			
Phone number		Fax number	
E-mail			

I would like to book a place at the UKRG Workshop 2016 as follows:		
	Cost	Tick if required
Delegate fee (to include lunch and refreshments)	£100	<input type="checkbox"/>
Bed and Breakfast accommodation for the evening of 14th January 2016	£75	<input type="checkbox"/>
TOTAL (£)	£ 0.00	

PAYMENT DETAILS

Payment may be made either by cheque (made payable to UK Radiopharmacy Group) or by BACS transfer (see details below)

Bank:	National Westminster	Sort Code:	60-02-35
Address:	Birmingham City Office 1 St Phillips Place, Birmingham B3 2PT	Account Name:	UK Radiopharmacy Group
		Account Number:	30684749
		BIC:	NWBK GB 2L
		IBAN:	GB05 NWBK 6002 3530 6847 49

CONDITIONS OF BOOKING:

Completed Booking Forms with details of accommodation requirements, together with a cheque (or confirmation of BACS transfer) for the full amount due, should reach the organiser (see below for contact details) no later than 31st December 2014.

Those wishing to enrol later than the time specified should contact the organiser in the first instance.

In the event of cancellation, refunds will only be given if WRITTEN NOTICE reaches the organiser:

- up to 28 days before the Workshop, 25% of the total fees payable will be charged
- less than 28 days before the Workshop, 100% of the total fees payable will be charged

(Please note, substitution of delegates will be accepted upon notification)

This booking form should be returned, together with a cheque or confirmation of BACS transfer, to the organiser:

Dr Adrian Hall
 Radiopharmacy
 The Royal Marsden NHS Foundation Trust
 Downs Road
 Sutton
 Surrey SM2 5PT

In the event of any queries, please either phone 020 8661 3308 or e-mail adrian.hall@rmh.nhs.uk