U.K. Radiopharmacy Group

NEWSLETTER
2011 Q4

UKRG INITIATIVES

UKRG Radiopharmacy Workshop 2012

The annual Bournville workshop will take place on the Friday 13 January. In past years the workshop has coincided with ^{99}Mo shortages and massive snowstorms, so holding it on Friday the 13th is surely tempting fate.

The theme this year is "Maintaining services in a challenging environment." Topics include:

- Compliance with regulations in manufacture of PET investigational medicinal products
- Optimising cost efficient use of generators
- Radiation dose limits to the eye
- Re-sheathing of needles (see item on the next page)
- Practicalities in commercial supply of FDG
- Modernising scientific/pharmacy careers

The afternoon session with be the familiar Controversy Corners which always generate lots of discussion (perhaps more heat than light, but a good chance to share ideas and vent frustrations.) Places are still available. Contact: Paul.maltby@rlbuht.nhs.uk

Molybdenum usage

Hidden away in an obscure marketing report are some interesting details on ^{99}Mo usage post crisis. The information comes from Lantheus Medical Imaging, which took on the former NEN/DuPont/BMS operations in North America, where Lantheus and Covidien are the two main suppliers of ^{99m}Tc generators. Lantheus was particularly hard hit in last year's shortage as their primary supplier was Chalk River, which was out of action for over a year. However, Lantheus has noted that following the return to normal supplies of ^{99}Mo, demand for generators has not returned to pre-shortage levels. Proposed reasons include:

- More efficient use of generators, or the realisation that generators were larger than necessary
- Loss of studies to other modalities
- Reduction in administered activities due to concerns about radiation exposure

There are also some interesting comments about the impact of generic sestamibi.

The report can be found at:
http://www.menafn.com/qn_news_story.asp?storyid=%7B8d3e5927-4b6f-40ce-bb96-2a51cfbb025e%7D

MOLYBDENUM

Molybdenum supplies

Availability of ^{99}Mo has been relatively stable for about a year. However, Chalk River will be shutting down for planned maintenance in the spring and this will have knock-on effects.

An unusual incident occurred on 16 November when a batch of bulk ^{99}Mo was rejected because total alpha activity exceeded the limit, the first time this has occurred in living memory. An investigation revealed that the contamination resulted from inadequate cleaning of the hot cell in which the target is dissolved at the beginning of the separation process.

WORKFORCE ISSUES

Royal Pharmaceutical Society open to non pharmacists

The functions of the Royal Pharmaceutical Society of Great Britain have been split into the General Pharmaceutical Council (licensing) and the Royal Pharmaceutical Society (professional body). This year the membership has voted to allow non pharmacists to join. This is a historic decision, after many years of protectionism. However, it has also been recognised that the Society needs paying members to make it viable, and membership is no longer mandatory for pharmacists (their licence is with the GPhC). There are vast numbers of people working in industry, quality assurance, oncology, and radiopharmacy who were not previously eligible but could now benefit from membership in the

Society. UKRG has maintained a relationship with the Society and some radiopharmacists are already members. The benefits of membership are still somewhat uncertain, but purportedly include participation in consultations and lobbying, expert advisory panels, society events, and a subscription to the *Pharmaceutical Journal*. I suspect the main advantages will be membership in a professional body and continuing education opportunities.

If you wish to apply for Pharmaceutical Scientist membership you will need to meet the following criteria:

- Have a degree (or equivalent) from a recognised institution
- Must be working in, or have worked in, an area of pharmaceutical science as outlined above
- Have at least two years experience in a pharmaceutical scientist role.

If you meet the eligibility criteria, you can apply to become a member online. Your application will need to be supported by two members of the Society. You'll also need to supply the following supporting information:

- A copy of your degree qualifications
- A portfolio of your relevant experience
- Details of your sponsors
- You may also wish to upload your CV, if you feel it supports your application

These benefits do not come cheaply as the annual fee is £192. However, it may well be worth it in order to have the post nominal SRPharmS.
www.rpharms.com

REGULATORY ISSUES

Re-sheathing of needles

It's a perfect example of unintended consequences. A well meaning and outwardly reasonable move to reduce the risk of transfer of blood borne infections by banning the recapping of needles has created a dilemma for radiopharmacy and pharmacy manufacturing units. We can't operate without recapping needles. During radiopharmaceutical production, when there is absolutely no risk of infection, we recap the needle in order to measure the activity in a dose calibrator without contaminating it. After drawing a dose we need to check the activity in a dose calibrator and often change the needle before injection. After injection we often need to check the residual activity; this does involve a risk of infection but the needle must be intact in order that an accurate measurement can be made in order to calculate the activity actually administered.

The European Council Directive 2010/32/EU "Implementing the Framework Agreement on Prevention from Sharp Injuries in the Hospital and Healthcare Sector between HOSPEEM and EPSU" must be implemented in UK legislation by 11 May 2013 (see Article 3(1)). Unlike certain other European countries (e.g. Denmark), the UK's domestic legal framework does not allow the social partners at Member State level to introduce their own, legally binding measures to implement this Directive.

HSE's initial proposal is to introduce a new set of Regulations (possibly called the Health and Safety (Sharps in Healthcare) Regulations 2013) to meet the requirements of the Directive. These Regulations would largely copy out the Directive. HSE's current planned timetable is:

- Formal public consultation on the proposed new Regulations in the summer of 2012
- Lay Regulations in Parliament – January 2013
- HSE guidance published (if required) – January 2013
- Regulations will enter into force – 5 April 2013

Clause 6 of the Directive says: "Where the results of the risk assessment reveal a risk of injuries with a sharp and/or infection, workers' exposure must be eliminated by taking the following measures, without prejudice to their order:

- Specifying and implementing safe procedures for using and disposing of sharp medical instruments and contaminated waste. These procedures shall be regularly reassessed and shall form an integral part of the measures for the information and training of workers (referred in clause 8),
- Eliminating the unnecessary use of sharps by implementing changes in practice and on the basis of the results of the risk assessment, providing medical devices incorporating safety-engineered protection mechanisms,
- The practice of recapping shall be banned with immediate effect"

It had been hoped that the risk assessment might give us an "out" but that is looking less hopeful. UKRG have been asked to supply data to the HSE on the prevalence of needlestick injuries within radiopharmacies, how these injuries occur, whether there are additional risks from the products being handled and whether there are any alternative safe procedures for recapping where there is no risk of injury. Representatives from the HSE and NHS Employers organisation will be attending the UKRG workshop in January.

While some radiopharmacies have recapping devices of some sort, they are not readily available commercially and they could only be used if the wording was changed to a ban on two handed recapping.

Recent MHRA inspections

Issues which have come up in recent inspections have included:

- Monitoring of alarms, procedure for actions to carry out in the event of a failure, how would you know if an alarm had sounded for a period during the night?
- Annual review of the Quality Management System should include licence updates and renewal of Technical Agreements
- Risk assessments for the chances of mixup of syringes, vials, etc.
- Clarification of release responsibilities with up to date list of authorised releasing officers
- Change control for new products or facilities

We were also informed that Mike Woodhall, who has been the MHRA representative at UKRG meetings for the last few years, is leaving the agency. Thanks for your contribution to the committee, Mike, and best wishes for the future!

Update on POM labelling

An astute reader of the Newsletter (is there any other kind?) noted an apparent discrepancy between the information given in the last issue and a statement on the MHRA website. We are attempting to obtain clarification of this issue.

Future EP monograph on Compounding of Radiopharmaceuticals

The European Pharmacopoeia commission has prepared a new chapter on compounding of radiopharmaceuticals. The draft is available at: http://www.eanm.org/upload/event_files/PhEu234E.PDF and is open for comments by the end of December. Comments may be sent directly to the EDQM or sent through the British Pharmacopoeia via myself.

Radiation protection training

The EU FP7 funded ORAMED project has released a series of videos and presentations on various aspects of radiation protection training: http://www.oramed-fp7.eu/en/Training%20material

UKRG ACTIVITIES

Postgraduate Course in Radiopharmacy

The timing of the "Easter course" was changed this year in order to better suit the timetable of the medics on the MSc in Nuclear Medicine Science for whom this forms the taught portion of their radiopharmacy module. The course is being held Tuesday 6 December to Friday 9 December in central London. The content was re-organised slightly so that each day (more or less) had a single theme: background/review, radiopharmaceutical chemistry, regulatory issues, and clinical radiopharmacy. There were 24 students in attendance. Thanks to the UKRG members who participate in this course and who have sponsored attendance by their members of staff.

Other ongoing activities

- Relaunch of the UKRG website is imminent, now hosted by BNMS
- The UKRG Radiopharmacy Handbook is being updated and will be available on the website
- Updated guidelines on radiopharmaceutical quality assurance will be issued shortly
- Drafting guidance to NHS Trusts on the transfer of radioactivity, radiopharmaceuticals, and the sharing of generators between hospitals in times of shortage
- Audit of suppliers of unlicensed products frequently comes up in MHRA inspections. A working party has been set up to establish a mechanism for audits on behalf of the NHS and academic centres. These audit reports would be shared with the public sector units
- The radiopharmacy audit document, used in BNMS and EL97/52 audits, is being updated
- Meeting with the MHRA to discuss the introduction of ^{68}Ga labelled agents.

MEETING REPORTS

European Nuclear Medicine Congress

The EANM meeting was held in Birmingham this year. Attendance was excellent and the weak pound drew continental shoppers to the Bullring. The Birmingham International Congress Centre (in the Symphony Hall complex) and overflow in the National Indoor Arena, linked by a marquee, performed very well as a venue. I was dubious at first, with its walkways to nowhere resembling an Escher drawing, but in the end I was wishing that we could hold the BNMS annual meeting there, though it would probably be prohibitively expensive. The one disappointment was that there were relatively few presentations by Brits, which must be a sign of the times.

Which is which?

The EANM Radiopharmacy Committee held an open meeting at which it updated us on its activities, which included the following:

- Drafting new guidance on automated synthesis devices and writing IMP dossiers, the latter activity being run jointly with the Drug Development Committee
- A working group on legislation, revision of the EU Clinical Trials Directive, and the validation of biomarkers as endpoints in clinical trials
- Educational activities include the Committee's first short course at EANM headquarters in Vienna, on PET methodologies
- It was reported that the European Radiopharmacy Certificate is now mandatory for radiopharmacy practice in Switzerland, the first country to officially recognise it
- The European Symposium on Radiopharmacy and Radiopharmaceutical in Nantes
- Relaunch of the VirRad website when it comes under the auspices of EANM

50th Anniversary of the Institute of Nuclear Medicine

The INM, originally based at the Middlesex Hospital and now at University College London Hospital, celebrated its 50th anniversary with a lecture and reception at the Royal Society of Medicine, Wimpole Street. The guest speaker was Professor Bruce Rosen of Harvard Medical School, who spoke on PET/MR and its future. The first PET/MR in the UK had recently been delivered to UCLH (photographic evidence was displayed) and will be operational early in 2012. The evening also coincided with the release of a book recording the historic firsts at INM and references the 1041 publications emerging from the unit.

INDUSTRY NEWS

Product shortages at GE

SeHCat capsules returned to the market on schedule, but it has been announced that Medronate (MDP) will not be coming back. There is currently one UK licensed supplier of MDP and two suppliers of HDP.

Zevalin

The FDA has approved an amended protocol for Zevalin therapy which removes the requirement for a pre therapy ^{111}In antibody scan for dosimetric purposes. This was never a requirement in Europe. It is anticipated that this will lead to increased use of Zevalin as the therapy will be less complicated to arrange and less expensive.

No more unlicensed products from Covidien

As Covidien has closed its depot in the UK, it no longer holds a wholesale dealer's licence and cannot import unlicensed products. This includes items such as ^{131}I sodium iodide injection and DMSA kits.

Siemens offers radiation website for general public

Siemens Healthcare has launched a new information source for patients undergoing imaging. The site, www.medicalradiation.com, features the fundamentals of the physics involved in the exams, an introduction to imaging procedures and notes on minimizing exposure to radiation, and a glossary that explains the most common technical terms.

Software demonstrations made easy

LabLogic Systems has made it easier than ever to see demonstrations of its software for drug metabolism, PET and radiochemistry. Every page in the software section of the company's website www.lablogic.com now has a 'Demonstration' button that links to online form where interested visitors can arrange to see exactly what a product can do – online or in-person. The company's software portfolio includes the application-specific LIMS Debra for ADME studies and PETra for radiopharmaceutical production and the Laura chromatography data collection and analysis system.

'Two in one' radio scanner/detector fits the budget (and the bench)

LabLogic's new combined Scan-RAM Radio-TLC scanner and Radio-HPLC flow through detector is already winning praise from university researchers for its money-saving 'two in one' characteristics.

The enthusiastic feedback has come from the molecular imaging laboratory in the Biomedical Imaging Center at the University of Illinois's Beckman Institute of Advanced Science and Technology. "We were initially seeking to purchase a separate TLC plate scanner and radio detector for our HPLC system, but the combined cost of two separate instruments was over our planned budget," says Dr Wawrzyniec Dobrucki, the laboratory's director. "LabLogic provided us with the solution with their Scan-RAM, which allowed us to save money and bench space as well as improving workflow by combining two instruments into one unit. In addition, LabLogic's Laura software made it possible for us to run the Scan-RAM and the HPLC system without purchasing proprietary software packages. Scan-RAM has been successfully used in both quality control and stability tests of new radiopharmaceuticals that we have synthesized in our laboratory."

Mid-sized gamma counters now available in the UK

Gamma counters used in hundreds of nuclear medicine and research laboratories around the world are now available in the UK for the first time, from LabLogic. Chicago-based Laboratory Technologies Inc (LTI) offers the Wiper series of gamma counters specifically designed for nuclear medicine and the Genesys Genii for research applications. Both are available in a range of affordable models for any budget, from basic, single-well counters to multi-detector versions which count up to 10 vials simultaneously – a ten-fold improvement in performance that represents a massive time saving over the course of a year and therefore early pay-back. At the top of the Genesys Genii range LTi offers a counter suitable for accurate measurement of high energy isotopes up to 2 MeV, which is ideal for PET labs. Full details of the Wiper and Genesys Genii gamma counters can be found on the LabLogic website.

Portable counter can measure PET isotopes and detect radioactive contamination

The Triathler portable single-well counter from LabLogic Systems, which offers liquid scintillation counting, gamma counting and detecting luminescence as standard, can be used for an even wider range of niche lab-based applications using appropriate optional accessories. The sodium iodide system, for example - which includes an external 2" x 2" well-type detector - achieves extremely good counting efficiency for gamma isotopes; ideal for measuring radiopharmaceuticals from PET laboratories and environmental samples.

UPCOMING MEETINGS

Chemistry for Imaging SINAPSE Spirit
6 Dec, Glasgow. www.sinapse.ac.uk

UKRG Radiopharmacy Workshop 13 Jan, Bournville. www.ukrg.org.uk

Current status and future directions of SPECT/CT imaging 16 Mar, London.
www.bir.org.uk

16th European Symposium on Radiopharmacy and Radiopharmaceuticals 26-29 Apr, Nantes, France. Abstract deadline: 5 Dec.
http://esrr12.eanm.org

British Nuclear Medicine Society annual meeting 30 Apr - 2 May, Harrogate. Abstract deadline: 6 Jan. www.bnms.org.uk

Society of Nuclear Medicine annual meeting
9-13 June, Miami. Abstract deadline: 6 Jan.
www.snm.org

World Molecular Imaging Congress and European Molecular Imaging Meeting
5-8 Sep, Dublin. www.wmicmeeting.org

European Nuclear Medicine Congress
27-31 Oct, Milan. www.eanm.org

From the Editor

I have been editing the UK Radiopharmacy Group Newsletter since 2001 and have decided that 11 years is long enough. Negotiations are in progress with someone who may accept this poisoned chalice, or rather this exalted position. My decision had been fermenting for some time but was brought to a head (to mix a metaphor) when I was persuaded to become the BNMS News and Views editor for *Nuclear Medicine Communications*. I'm not jumping ship but taking the opportunity to throw my toys out of a larger pram (to further mix metaphors).

Thanks to those who have given me positive feedback over the last 11 years, and those who have tried to keep me on the straight and narrow.

Au revoir!

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Issue 2011 Q4 Published 6 December 2011	This and previous issues of the Newsletter are available from the UKRG web site and are posted in the library section at www.VirRad.org