U.K. Radiopharmacy Group

NEWSLETTER
2007 Q1

## UKRG EVENTS

### Report on Bournville workshop 2007

The workshop took place on Friday 12th January. With a flurry of late registrants, attendance matched the high numbers seen in recent years. The title of the day was Radiopharmacy Validation and Practice Update. Geoff Jones started us off with Validation Plans in Aseptics and Radiopharmacy. This was followed by presentations from LabLogic on validation of laboratory equipment and software and from Veenstra/Britec on validation of radiopharmacy software. Following a much needed coffee break, Bill Thomson spoke on implementation of the NPL good practice guide for maintaining dose calibrators and Andy Bradley updated us on the new transport regulations due to take effect this year. This was followed by Jim Ballinger with some nonsense on urban myths in radiopharmacy. During the lunch break there was an opportunity to visit displays from LabLogic, PaxSys, and Veenstra/Britec. The afternoon session consisted of controversy corners which are reported in Appendix 1. All in all it was a good day and those who missed it are encouraged to attend next year.

### Postgraduate course in radiopharmacy

The annual postgraduate course in radiopharmacy, sometimes known as the Easter course, was held 12-15 March at King's College London. Attendance this year was 22, including two people on the PTQA course and three medicines inspectors from the Netherlands.

### BNMS annual meeting 2007

The radiopharmacy stream at the Manchester meeting on 20 March ran to two full sessions encompassing 11 proffered papers. Topics ranged from peptide synthesis and labelling to quality control to small animal imaging. Let's try to maintain this level of participation at next year's annual meeting in Edinburgh.

## UKRG INITIATIVES

### Sampson's Textbook of Radiopharmacy

The third edition of the textbook was published in 1999 and is now out of print. This presents a problem because it is the textbook for the PTQA radiopharmacy module, for the Easter course, and for nuclear medicine registrars up and down the country, as well as being a useful reference text for people in the field. The publisher is not interested in issuing a fourth edition, but the UKRG wants to make it happen. A full day was spent discussing the content of the new edition in January prior to the Bournville meeting. This will not be merely an update but a complete rewrite. Tony Theobald has agreed to be the editor. Chapters will be assigned shortly with a fairly tight deadline, so it is hoped that the new edition will be out within a year. The final format has not been determined and electronic as well as hard copy formats are being investigated. In honour of its original editor, the book with now be officially known as *Sampson's Textbook of Radiopharmacy.*

### Radiopharmacy Handbook

Revision of the UKRG Radiopharmacy Handbook is underway. The work has been divided up among UKRG members, with some making more progress than others (guilty as charged). Malcolm Frier will be compiling and editing the final version. It is hoped that portions of the revised Handbook will appear on the website shortly.

## WORKFORCE ISSUES

### Registration of radiopharmaceutical scientists

The Health Professions Council has sent a non-committal reply to the approach by BNMS and UKRG requesting a voluntary register for radiopharmaceutical scientists. Undeterred, the UKRG will now approach the Association of Clinical Scientists to set up a training package which can then be taken to HPC for registration.

## REGULATORY ISSUES

### Qualified Persons (QP)

A meeting was held on 7th November between the Royal Pharmaceutical Society and various representatives of NHS manufacturing units, the quality assurance committee, and the UKRG to address the issue of QPs within the NHS. Among the points made were:

- Few hospitals have full manufacturing licences; most NHS manufacturing occurs under specials licences which do not require a QP.
- However, an IMP licence requires a QP and there are no provisions for awarding of new QPs. The transitional period has lapsed and institutions which did not put the names of QPs forward are unable to become involved in IMPs.
- Concern was expressed that hospital candidates may be told at the viva that they needed to acquire further experience. Pharmaceutical companies might not wish to provide placements due to confidentiality issues.
- Advice was sought on how hospital candidates might be able to gain additional experience. It was highlighted that the practical experience does not necessarily have to be industry-based. Experience counted wherever it was gained, including under a specials licence. The assessment panel looked for application of knowledge and Quality Management System principles across different dosage forms. Anyone working under a manufacturers' authorisation could in theory satisfy the Study Guide requirements.
- It was highlighted that hospital candidates might wish to consider increasing their knowledge of pharmaceutical packaging and Active Pharmaceutical Ingredients, which might be obtained via generic manufacturers as opposed to large pharmaceutical companies. Experience under a full manufacturers' licence could relate to excipients as well as active products.
- Concern was expressed that the NHS might not be able to fund QP training and some of those working in the IMP area might not have the requisite experience to satisfy the Joint Professional Bodies eligibility requirements.
- The specific problems related to QPs in radiopharmacy were raised, but no solutions were proposed.

### Administration of pharmaceuticals in nuclear medicine

A revised document which replaces the previous patient group directions has been posted on the BNMS website (www.bnms.org.uk). This document rationalises the previously conflicting regulations and allows groups such as technologists and clinical scientists not included in the original legislation to administer radioactive and non-radioactive pharmaceuticals as part of a test. From the home page go to Regulatory Issues, then Pharmacy Related.

### Transport of radioactive materials

The current RAMRoad regulations are being combined with other transport regulations into the Carriage of Dangerous Goods Regulations 2007. However, the good news is that there will be no changes to design requirements, labelling and placarding, allowable contents, emergency arrangements, or responsibilities. Current derogations will continue to apply, such as the use of a fireproof notice rather than ADR orange plates and reduced requirement for fire fighting equipment for UN 2910. The anticipated effects can be summarised as follows:

- Consignment notes and certificates of conformity must reference the new regs.
- Quality programmes must show evidence of a review of the transport operation against the new regs.
- There are explicit requirements for "general awareness" training, though details are to be specified.

(Thanks to Andy Bradley who presented this material at the Bournville workshop.)

### Regulation of health professionals

As those of you who are registered as pharmacists will know, the Royal Pharmaceutical Society of Great Britain currently functions as both a regulatory body and a professional body, but these two roles are to be separated. The General Pharmaceutical Council (equivalent of the GMC) will become the new regulatory and disciplinary body, while the Royal College will become the professional body. A meeting of ancillary organisations related to pharmacy on 15th March hammered out The Waterloo Agreement which states how these organisations should move forward. Among the points most relevant to radiopharmacy are that the Royal College body should:

- Have a membership broader than the GPC and should include non-pharmacists working in related areas.
- Operate a Faculty system to take account of the diverse fields of practice within the pharmacy profession.
- Recognise different levels of education, expertise and specialisation within its membership structure, by means of peer group accreditation.

The UK Radiopharmacy Group has endorsed this agreement.

## PRODUCT/INDUSTRY NEWS

### $^{32}$P sodium phosphate

Following the withdrawal of $^{32}$P sodium phosphate by GE Healthcare at the end of the year, Diagnostic Imaging Ltd (DIL) has obtained a wholesale importers licence and is able to import $^{32}$P as a special. www.diagimaging.com

(Tyco was planning to import $^{32}$P sodium phosphate but it proved to be too expensive.)

### Hetastarch

Baxter is discontinuing its hetastarch 6% (hespan). However, ampoules are available as specials from at least two NHS pharmaceutical manufacturing units. Please be aware that "not all hetastarch is equal" for sedimenting red blood cells.

## INFORMATION

### Free access to journals

Further to the note in the last Newsletter that electronic access to *The Journal of Nuclear Medicine* will be free for all issues more than one year old. Although the electronic format extends only back to 2000, earlier volumes have been scanned and are available as (large) PDFs back to Volume 5 in 1964. Look for them at www.snm.org.

One of the bizarre papers in the first year available describes a method to maintain a constant body burden (for radiotherapeutic purposes) of $^{90}$Y DTPA over 8 hours by collecting and reinfusing the patient's urine. Up to 560 mCi (21 GBq) was administered, resulting in a radiation dose of 200 rads to the lymph nodes.

## UPCOMING MEETINGS

**17th International Symposium on Radiopharmaceutical Sciences** 30 April – 4 May, Aachen, Germany. www.fz-juelich.de/inc/isrs2007

**Society of Nuclear Medicine** 2-6 June, Washington, DC. www.snm.org

**British Nuclear Medicine Society** 3-4 September, London. Abstract deadline: 28 June. www.bnms.org.uk

**European Nuclear Medicine Congress** 13-17 October, Copenhagen. www.eanm.org

**British Nuclear Medicine Society** 12-14 May 2008, Edinburgh. www.bnms.org.uk

## *Note from the Editor*

Despite my New Year's resolution that every effort would be made to keep publication of the Newsletter on schedule, I have failed miserably to achieve this. However, hope springs eternal, etc., and I should get back on track with the next issue.


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| Issue 2007 Q1 Published 11 April 2007 | 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 |

# APPENDIX 1: CONTROVERSY CORNERS 2007

## Validation of expiry times of labelled kits other than manufacturers recommendations

- Don't extend anything
  - Legal issues
  - How much validation is required?
  - Are there adequate resources to support this on an ongoing basis?
  - ARSAC certificate holder must be informed
- How much validation is required?
  - Radiochemical purity (RCP) measurements over time range
    - How many measurements?
    - How long? Weeks or number of kits?
    - Variable
  - Can we use other peoples' validation?
    - Published data
    - Too busy to carry out validation
  - Is carrying out RCP measurements enough?
  - Biodistribution on scans
    - Field of view must be adequate to see potential impurities (e.g. stomach, thyroid)
  - Permission of ARSAC certificate holder
- If expiry "in house" determination
  - Unlicensed product?
  - Legal issues
  - Patient consent?
- Expired kits
  - Generally not used
  - RCP measurements
  - Pragmatic approach
    - Professional judgement
    - Risk management
- Sterility
  - Considered not to be an issue with $^{99m}$Tc products

## Packaging for transport of radioactive materials by road

- Approved containers with valid certificate of approval
  - Expensive – cost of testing included
  - Test "in house" on receipt?
    - Radiation protection
    - If modify, certificate may no longer be valid
  - Annual documented checks on container
  - Signoff
    - Must visually check still suitable for Type A
      - Not necessary to document but tick box on transport document could be used
  - 10 year life, would probably not recertify
  - For return must be labelled as empty package
- Re-use of packages
  - Using Type A as excepted packaging is OK but must document that it is suitable
  - Should not be re-used as Type A
  - If re-used as Type A (e.g. generator return) company must validate
- Labelled blood products
  - May be easier to despatch labelled blood as Type A even though would fall into excepted range
  - Receipt of blood for labelling
    - Must be in approved container labelled UN 3373
    - Available from Daniels (below) and other suppliers
    - Check with Pathology

see http://www.daniels.co.uk/pages/productsearch/transport/transportset.htm

## Sodium chloride injection for kits: what's the problem?

- For a number of years there have been reports of sporadic problems with RCP of $^{99m}$Tc-MAG3 and these problems have been attributed to the source of saline
- Glass ampoules
  - No problems have been reported
  - Safest to use glass
  - However, there are Health & Safety issues with opening of glass ampoules (over the years your editor has had a number of serious cuts due to this)
  - Extra saline vials from generator could be used (septum rather than ampoule)
- Plastic ampoules
  - Occasional problems have been reported but no specific component has been identified as responsible
  - Very recent news (presented in full at Manchester BNMS meeting in March; see: Millar AA *et al.* The effect of preparing $^{99m}$Tc-MAG$_3$ using sodium chloride injection from plastic ampoules that have been exposed to light. *Nucl Med Commun* 2007;28(3):A14-A15.
    - Exposure of plastic ampoules to light can result in product failure
    - All manufacturers are implicated but some degrade more quickly than others
    - Solution: store plastic ampoules of saline in cardboard box until immediately prior to use

## Radiolabelling of blood cells: optimising techniques

- Avoiding risks
  - Blood sample contaminates other products
    - Separation in time and space
  - Blood sample contaminates operator
    - Avoid use of needles
  - Operator contaminates blood
    - Minimal risk with proper procedures for use of isolator or biological containment cabinet
  - See report on how bad practice can lead to catastrophic results: *Journal of the American Medical Association*, 25 October 2006, vol 296, no 16, pages 2005-11, and referenced in the *British Medical Journal,* 4 Nov 2006, vol 333, page 963.
- Improving turnaround time
  - When to add sedimenting agent (Hespan)?
  - Where to sediment blood?
    - In transit, so cells will be sedimented when received in radiopharmacy

## $^{131}$I Iodine therapy: capsule or liquid?

- Advantages of capsule
  - Ease and safety of handling
  - Avoids contaminated drinking straw
  - Less waste
  - Lower finger dose due to less handling
  - Quicker
  - Give with warm drink to aid capsule dissolution
  - Cough (nerves)
  - Thiosulphate
- Advantages of liquid
  - Flexibility
  - Capsules sometimes arrive too high
  - Xe gas and volatile radioiodine
  - Some patients can't swallow capsules
  - Psychiatric patients
  - Cheaper
  - Some patients may require injection
  - Avoids split capsule
  - Concerns about gelatin capsules: vegetarians, kosher, TSE
  - Veterinary use
  - Danger of swallowing plastic insert with capsules (it has happened!)
  - More liquid waste but less wastage
  - Scarier to give than capsule because of risk of spillage

**Is there a place for practice-based research in radiopharmacy?**

- Main limitation: time
- How to disseminate results?
  - Local meeting
  - UKRG
  - BNMS spring or autumn meeting
  - VirRAD
  - Publication
  - Need for "friendly audience" for presentation
- Concerns
  - Insecurity about importance and quality of work

## APPENDIX 2: ON A LIGHTER NOTE

Bournville, home to our annual workshop, has been in the news recently.

6 METRO Tuesday, March 27, 2007

# Teetotal village wins Tesco booze battle

BY MIKE TAIT

RESIDENTS of a famous teetotal village founded by Quakers have won a battle to prevent Tesco selling alcohol near their homes.

Birmingham City Council rejected the supermarket's application for a licence to sell alcohol at one of its Tesco Express stores near Bournville.

The area has been completely free of pubs and off-licences since it was founded by Quaker chocolate baron George Cadbury in the 1890s.

The supermarket wanted to open an off-licence on the edge of Bournville Village estate, but councillors decided this could worsen existing anti-social behaviour and underage drinking.

More than 1,000 people signed a petition against the licence, which was proposed without consultation.

Cllr Nigel Dawkins, who led the opposition to Tesco, said: 'This is a fantastic result. This shows Tesco that they have to talk to communities and they cannot just walk over them. It is a victory for Bournville.'

Resident Martin Sketchley added: 'I just want a safe environment for my kids to grow up in and the licence would have compromised that.'

A spokesman for Tesco said: 'We are disappointed by this decision and are considering our options.'

Mr Dawkins said he was confident any appeal would be overturned.




## A history of dryness

**BOURNVILLE village was founded by George Cadbury in 1895 as a utopian community for workers at his factory. It was built according to the Quaker principles of sobriety and social justice. Cadbury was not against alcohol but fought to change the living conditions which drove the poor to drink. In contrast to the harsh industrial Victorian lifestyle, Bournville workers lived in pleasant homes among green spaces, under laws designed to maintain that environment.**