U.K. Radiopharmacy Group

NEWSLETTER
2009 Q3

## MOLYBDENUM CRISIS

### International

- The Chalk River reactor has now been drained and properly inspected. The good news is that engineers feel the leak can be repaired (there had been some doubt about this). The bad news is that the reactor will not be back in operation until the first quarter of 2010.
- By that time, Petten will be shut down for major repairs likely to take 6 months, thus the international supply will be extremely tight.
- The Australian reactor has been slow to ramp up production and is not yet exporting $^{99}$Mo.

### National

- GE has altered its reference days in order to co-ordinate production with receipt of their supply of $^{99}$Mo, rather than letting it decay away for a day or two on the shelf. (Remember, we lose 22% per day.) This means an end to weekend deliveries, which have been a way of life for as long as anyone can remember.

### Medium term

- In the USA, the American Medical Isotopes Production Act has been introduced and is being debated by Congress. There is a proposal to spend US$163 million over 5 years to create a domestic supply, likely by upgrading the Missouri reactor.
- The Canadian government has convened an expert panel to consider more than 20 proposals for far reaching projects and to make recommendations by the end of November.
- The reactor at the Technical University of Munich has applied for funding to upgrade for $^{99}$Mo production. They claim that an investment of (only) €5.4 million would allow them to supply 65% of Europe's needs within 5 years.
- Advanced Cyclotron Systems Inc (ACSI) claims that their 24 MeV cyclotron could be routinely producing $^{99m}$Tc by irradiation of $^{100}$Mo targets within 18 months (there has been some slippage – the first announcement several months ago said within 15-16 months).

### Sources of information

- Dewi Lewis's report is in the October issue of *Eur J Nucl Med Mol Imaging*
- The massive report commissioned by the US National Academy of Sciences, entitled "Medical isotope production without highly enriched uranium" is available for download at: www.nap.edu/catalog/12569.html
- Weekly updates on the status of repairs at the Chalk River reactor are available at: www.nrucanada.ca
- The BNMS website (www.bnms.org.uk) remains the most useful source of current information. News items and communications from manufacturers are posted in a timely fashion. In contrast, the EANM "supply crisis" link hasn't been updated since 17 June!

## UKRG INITIATIVES

### Bursary offered for ESRR15

The UKRG is offering a bursary in the form of registration for the 15th European Symposium on Radiopharmacy and Radiopharmaceuticals to be held in Edinburgh in April. The bursary will be awarded to the author of an abstract accepted for presentation at the symposium. The objective is to encourage research presentations by junior staff within the NHS.

Eligibility criteria:

- The applicant must be listed as first author
- It must be the applicant's first presentation at an international conference
- The applicant must be a junior member of staff (band 7 or lower) or student at a UK institution
- The topic must be within the realm of radiopharmaceutical science and/or practice.

Application process:

- Deadline 14th December
- Abstract to be prepared in format specified for ESRR15 (to be announced shortly)
- Copy of abstract submitted to UKRG c/o paul.maltby@rlbuht.nhs.uk
- Statement from supervisor that institution will pay the applicant's travel expenses (not included in bursary)

As sufficient funds are available for only one bursary, applicants are encouraged to submit their abstract via the normal route if they wish it to be considered for presentation even if they are not the winner of the bursary.

## Bournville workshop 2010

The annual workshop will again be held in the sleepy (and dry) town of Bournville near Birmingham. The date is Friday 15th January. Presentations will include: $^{99}$Mo from ore to generator; an update on the uses of contrast media in radiology; the future for PET/SPECT tracers in nuclear medicine; and an update on the MHRA review of unlicensed medicines. The afternoon parallel sessions will look at aspects of quality assurance: end of session broth fills; sterility testing; and radiochemical purity testing. Last year the workshop was fully subscribed so please register early. If you haven't received a mailing please contact paul.maltby@rlbuht.nhs.uk.

## Radiopharmaceutical quality assurance

The UKRG most recent guidance on QA of radiopharmaceuticals was issued in 2001. A working party is updating this guidance in light of recent developments. The results of Newsletter surveys on radiochemical purity testing and sterility testing are being taken into consideration. A meeting was held in May, another is scheduled for November, and the entire committee with consider the issue in January. This will also be a topic at the Bournville workshop. It is anticipated that updated guidance will be issued early next year.

## Survey of clinical activities

An embarrassingly long time ago a survey was conducted via this Newsletter, the results of which have finally been located and are seeing the light of day in Appendix 1.

# REGULATORY ISSUES

## Feedback from recent MHRA inspections

Among the topics which have featured are:

- Microbiology (particularly if the inspector happens to be a microbiologist); actions in the event of a micro failure; justification of positioning of plates.
- Annual test of recall procedure. (An interesting anomoly: if a consignment is en route it cannot be recalled as this would contravene the transport regulations, having been duly consigned.)
- Service level agreements for quality assurance, maintenance, etc.

# INDUSTRY NEWS

## Colloids for sentinel node studies

The Nanocoll crisis which was bubbling at the time of the last Newsletter was resolved after intervention at a high level, but it does serve to remind us of the fragility of supply of items with a single producer.

A comparison of the properties of alternative (unlicensed) $^{99m}$Tc colloids which have been used for sentinel node detection in Europe was included as an appendix to the last Newsletter. At the time there was little clinical information about the two albumin colloids from Medi-Radiopharma in Budapest. Gergely Janoki posted the following information on VirRad (edited slightly for clarity):

"The following additional information related to sentinel radiopharmaceuticals could be useful during the shortage of Nanocoll. Medi-Radiopharma Ltd manufactures two types of sentinel agents and their features are as follows:
A: Nano-Albumon kit containing HSA nanocolloid particle size 80% below 100 nm. Median particle size 20-60 nm. Kit stability: 18 months stored at 2-8 C. The labelled compound is stable for 6 hours if stored below 25 C.
B: Senti-Scint kit with 80% of particles between 100-600 nm. Median particle size 100-250 nm. This particle range called optimal for sentinel studies.

Both kits have been manufactured and licensed for more than 10 years and have an identical composition. Only the particle sizes are different. Nano-Albumon is mainly used for melanoma studies and Senti-Scint for breast studies. The number of nodes visible by medium sized particles (Senti–Scint) are much lower than when small size particles are used. With the larger particles, the activity ratio between sentinel and non sentinel nodes is high and therefore surgeons find sentinel node quickly.

For manufacturing both kits 20% HSA is used. Manufacturer of HSA are identical with originator product and other protein based radio-pharmaceuticals (e.g. Macrosol). Kits are manufactured, packed and released at cGMP conditions and as registered and non registered products are used in more than 10 countries in and outside Europe (e.g. Germany, Austria, Czech Rep, Slovakia, etc) for more than 10 years. During this time nearly 1 million patients were studied. For more info check Medi-Radiopharma Ltd website at www.mediradiopharma.com"

## TLC chromatography media

The withdrawal of ITLC-SG by Pall Gelman has led to a mad scramble for alternatives, particularly since ITLC-SG is (was) used in methods required in pharmacopoeias and recommended by manufacturers.

As reported in a previous Newsletter, Varian supplies media equivalent to the previously withdrawn ITLC-SA. The product is known as glass microfibre chromatography paper impregnated with silicic acid (GMCP-SA).

Varian has been working with radiopharmaceutical manufacturers, particularly GE Healthcare, to validate new RCP methods using GMCP-SA. Indeed, GE has distributed to customers details of new methods for tetrofosmin (Myoview) and exametazime (Ceretec). Varian is also consulting users on the most useful size of strips to supply, as it currently comes in sheets of 11x30 cm.

Contact: James Stratta, Sales Professional, Consumable Products, Varian Inc., 10 Mead Road, Oxford Industrial Park, Yarnton, Oxford, OX5 1QU, fax: 01865 841 945, tel: 01865 291 500. The website is: www.varianinc.com and the UK office is uk.consumablesales@varianinc.com

## New developments in therapy

- Radium-223 (Alpharadin), the alpha emitter under development by the Norwegian company Algeta for treatment of bone metastases, has shown promising results in Phase II studies. Bayer has now bought the rights to bring the product to market.
- Zevalin has been approved in the USA as first line therapy for non Hodgkin's lymphoma, a much broader indication than the current relapsed or refractory NHL. This could give a much needed boost to a product which has been struggling in the marketplace.

## PEOPLE

- At its summer meeting the UKRG committee welcomed Grace Gough from Oxford.
- A former committee member, Maggie Cooper, has returned from two years in China and is now working in the Division of Imaging Sciences at King's College London.
- *Applied Radiation and Isotopes* has announced the appointment of three new receiving editors. Of most relevance to us is Prof Roger Schibli from Zurich, who was a guest speaker at this year's BNMS meeting in Manchester. Roger is perhaps best known for developing the technetium/rhenium tricarbonyl (IsoLink) technology and more recently has been involved in application of "click" chemistry to radiolabelling.

## UPCOMING MEETINGS

**Molecular Imaging in Radiation Oncology (MIRO)** 18-20 Mar, Brussels. Abstract deadline 28 Oct. www.estro.org

**15th European Symposium on Radiopharmacy and Radiopharmaceuticals** 8-11 April, Edinburgh. Abstract deadline 14 Dec. http://esrr10.eanm.org/

**British Nuclear Medicine Society spring meeting** 26-28 April, Harrogate. Abstract deadline 11 Jan. www.bnms.org.uk

**Society of Nuclear Medicine annual meeting** 5-9 June, Salt Lake City. www.snm.org

**World Federation of Nuclear Medicine and Biology Congress** 18-23 September 2010, Cape Town, South Africa. Abstract deadline 15 Mar. www.wfnmb.org


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## APPENDIX 1: SURVEY OF CLINICAL ACTIVITIES

I expect that most people will have forgotten by now, but quite some time ago (about 3 years) we conducted a survey of the involvement of radiopharmacists/radiopharmaceutical scientists in clinical activities within the Nuclear Medicine department. The survey was devised by Sanjay Patel and Jilly Croasdale, and the results were collated by Sanjay but cleverly hidden on the shared drive and did not come to light until recently. On several occasions I have been asked "When will we see the results of the survey?" to which I have replied "As soon as I find them." Well, that moment has come and herewith we reveal the outcome.

This survey was distributed with the UK Radiopharmacy Group newsletter. Seventeen responses were received and the results are tabulated below.

| Type of institution | Responses | Number of staff | Responses |
|---|---|---|---|
| Teaching hospital | 11 | 0 | 3 |
| District general | 5 | 1-2 | 9 |
| Acute | 0 | 3-5 | 4 |
| Other | 1* | Not stated | 1 |

*Clinical technologist

To what extent do radiopharmacists/radiopharmaceutical scientists cover the following clinical activities in your Nuclear Medicine department?

| Q# | Clinical activity | Fully | Partially | Never |
|---|---|---|---|---|
| 1 | Reporting | 0 | 1 | 16 |
| 2 | Checking scans prior to patient leaving department | 1* | 0 | 16 |
| 3 | Checking patient medication on day of scan – relevant drug history, allergies | 4 | 2 | 11 |
| 4 | Checking patient medication prior to booking scan | 3 | 3 | 11 |
| 5 | Authorising medication to be stopped | 5 | 4 | 8 |
| 6 | Arranging medication to enhance scan | 5 | 5 | 7 |
| 7 | Giving advice to patients on radiation protection after test | 1 | 3 | 13 |
| 8 | Running clinics (e.g. thyroid) | 2 | 0 | 15 |
| 9 | Authorising referrals | 1 | 0 | 16 |
| 10 | Administration of diagnostic or therapeutic radiopharmaceuticals | 1 | 3 | 13 |
| 11 | Involvement in planning of care pathways | 0 | 6 | 11 |
| 12 | Counselling patients on perceived hazards of radiation | 1 | 5 | 11 |
| 13 | Follow-up after an adverse event | 10 | 5 | 2 |
| 14 | Checking blood counts prior to therapy | 0 | 4 | 13 |
| 15 | Dose calculation checks (e.g. paediatrics, renal impairment, etc.) | 6 | 7 | 4 |
| 16 | Dealing with adverse drug reactions | 6 | 9 | 2 |
| 17 | Advising clinicians/patients on how medications may affect scans | 4 | 10 | 3 |
| 18 | Helping to write protocols on which medications to stop | 4 | 8 | 5 |

*Clinical technologist