U.K. Radiopharmacy Group

NEWSLETTER

2019 Xmas edition

In this issue…

Welcome to the Christmas Edition of the UKRG Newsletter!

BOURNVILLE WORKSHOP 2020

As reported in the last newsletter, in a break from time-honoured traditions the 2020 UKRG workshop will be held in February rather than the usual early-January slot. It is hoped that this will make attendance easier as the Christmas work backlog will hopefully have been cleared by then! If you do attend then please use the feedback forms to let us know if you think this change is for the better or worse. The date for your diaries is **Friday 7th February 2020**. Some traditions have to be kept and so the workshop will be in the usual venue of the Beeches Centre in Bournville, Birmingham. The full programme is shown at the end of this newsletter and is also available through the UKRG website. As with recent years, registration can be done electronically by following the links from this website. The preferred method of payment is by PayPal but, if you are getting your organisation to pay, then please check that the finance contact details held by your procurement department are for Helen Wilson in Leeds Teaching Hospitals NHS Trust.

Please do try to attend this workshop. Not only is it a packed programme with lots of useful guidance on legislative compliance in radiopharmacy, but it's a great opportunity to meet others across the country working in this specialist field.

BREXIT UPDATE

And so the saga continues……
Given the result of the General Election on the 12th December it looks like the EU-agreed Brexit date of January 31st 2020 will go ahead. However, details of the trade agreement with the EU are still to be decided and the future possibility of leaving the EU without a deal still remains. For the latest information, readers are encouraged to keep up to date by following developments on the BNMS website which updates articles on this issue regularly:

https://www.bnms.org.uk/page/BrexitEuratom

As mentioned in previous newsletters, discussions in relation to Brexit are common in the UK and EU mail-bases that we have provided links to below. So, if you have not already joined one of those, we encourage you to do so.

Radiopharmaceutical suppliers and Trusts have previously developed contingency plans to mitigate delays and disruptions to the supply of radiopharmaceuticals in the event of a no-deal Brexit. These were put in place for the April and October 2019 deadlines and are likely to be adopted in the future if there appears to be the possibility of a no-deal Brexit. The Royal College of Radiologists, British Nuclear Medicine Society and UKRG issued a document in March 2019 on *Practical advice for radiopharmacy and nuclear medicine services in the event of a no-deal Brexit*. This can be found on the following link:

https://www.rcr.ac.uk/sites/default/files/no_deal_brexit_planning_guidance_for_nuclear_medicine_teams_march_2019.pdf'

Communication with suppliers as well as radiopharmacy and nuclear medicine (NM) colleagues is of key importance when planning local contingencies to help reduce the likelihood of delays and disruptions.

PULMOCIS (MACROSALB) SPC CHANGE AFFECTING PARTICLE NUMBERS

If you use this product then hopefully you will already have noticed that the SPC has changed significantly. Although the formulation remains unchanged, the changes to the SPC (in particular those relating to particle numbers) have had a significant impact on how the product can be used in the Nuclear Medicine department if using it as a licensed product. There doesn't seem to have been any warning about these changes from the supplying company and no explanation has been given as to the drivers for the change. This is disappointing considering the potential impact on usage. This highlights the importance of units having good processes in place for checking the SPC version number on all new deliveries of kits. Where a change in version number is identified then a detailed comparison against the previous version should be undertaken to establish all content changes. Being a member of the UKRG mailbase is also a good way to get an early heads-up on issues such as these affecting the radiopharmacy community.

Key changes to Pulmocis SPC and effect on usage

Administration method

There is more detail on how the tracer should be administered. As well as the existing advice about agitating the syringe and not drawing back blood, it now states that the patient should cough and take several deep breaths prior to the administration. It also states that the administration should be given over 3 to 5 respiratory cycles or for at least 30s. This seems rather impractical considering the small volumes being injected for perfusion lung scans.

Particle numbers

The minimum and maximum particles that should be administered to standard and compromised patients (R-L shunt or Pulmonary Hypertension) have changed. The main issue is in terms of the maximum particle limit, which is now 300,000 for standard patients (or potentially 700,000 depending on how you interpret the SPC) and 200,000 for those with a R-L Shunt/PHT. Given the maximum kit activity limit, these revised restrictions on particle numbers limit the useful life of the kit, particularly for the compromised patients where it becomes necessary to administer the tracer relatively soon after production.

Some of the UKRG committee members have developed Excel spreadsheets for their departments in order to help in the calculation of particle numbers and the resultant time restrictions etc. If you would find it useful to modify one of these for use in your own department then please contact the newsletter editor or your regional UKRG contact who will be able to put you in contact with the relevant people. It is important to perform validation of any spreadsheets used to calculate administered doses and volumes.

Minimum activity in kit

The minimum kit activity has now been reduced to 400 MBq. This makes the product practically difficult to use in gastric emptying studies where small activities are required (ARSAC DRL is 12MBq). To make this easier to deal with when making the radioactive meal, NM staff could be advised to draw up some water/saline into the syringe following withdrawal of the MAA from the vial. Alternatively the syringe could be flushed out with water/saline after injecting the neat MAA into the meal.

For full details of all the changes please refer to the SPC

IRR 2017: EXPECTATIONS OF THE HSE AND ONR INSPECTORATE

A number of new requirements were introduced with these revised regulations. However, the impact of these changes was only fully understood when users and regulators began to implement them. For radiopharmacy this has meant significantly increased expectations by HSE and ONR inspectors. A summary of the key changes to the previous version of IRR is given below, along with the increased expectations of the relevant inspectorate:

Regulations 5, 6 and 7 are concerned with a new risk based system of informing the HSE that you intend to work with ionising radiation.

- Low risk practices (eg. low level laboratory users) must ***notify.***
- Medium risk practices (eg. diagnostic X-ray) must be ***registered*.**
- Higher risk practices including both the manufacture and administration of radiopharmaceuticals must receive ***consent***.

This is done online by answering a series of questions. Registration and Consent attracts a £25 fee.

Regulation 8 – Risk assessment. The real change here lies more in the expectations of the regulator. The HSE and ONR (in respect of transport), will be looking for risk assessments which identify all the exposed groups e.g. radiopharmacy production staff, assistants, and

staff or contractors involved in cleaning and maintenance. The dose-rates and doses to each group must be used to determine the specified precautions, training and the need for classification.

Regulation 12(3) requires the dose to members of the public that could be exposed to be estimated. Members of the public will include non-radiopharmacy/non-department employees, as well as patients and visitors occupying areas adjacent to the radiopharmacy. The dose assessment should preferably be undertaken by means of measurement over a representative period of operation.

Regulation 13: There must be a Contingency Plan for all reasonably foreseeable accidents identified in the risk assessment. For a radiopharmacy this is likely to include, but not limited to, spills within the LAFC/isolator, punctured gloves, and mechanical failure of shielded containment, generator hoists and auto dispensing equipment. Whenever a Contingency Plan is implemented a detailed investigation must be undertaken and documented. Contingency Plans must be rehearsed and the learning from each rehearsal recorded. The regulator may ask to see a programme of future rehearsals.

Less significant events will require implementation of parts of a contingency plan and should be included in department records.

Regulations 12, 21 and 22: The eye dose limit has been reduced from 150 mSv/year to 20 mSv/year, with a classification threshold of 15 mSv. The need to designate radiopharmacy staff as classified workers must be considered in the risk assessment, taking into account routine (optimised) doses and doses as a result of a likely accident. The risk assessment and local rules must address extremity dosimeter wear position to ensure the maximum doses received by the hand/skin are understood.

Outside Workers:
The term Outside Worker is not new, but now applies to Classified and Non Classified workers. They are employees entering a designated radiation area controlled by another employer. The employer in control of that area must ensure that the outside worker receives the same protection, training, dosimetry etc, as one of their employees. Clearly the majority of the requirements will apply when the outside worker enters a Radiation Controlled Area.

Radon: IRR2017 applies if the annual average concentration exceeds 300 Bq/m3. The previous regulations applied if the concentration exceeded 400 Bq/m3 averaged over a 24 hour period.
They are in effect broadly the same.

Medical exposures: Regulations concerning medical equipment and Carers and Comforters have relocated to IRMER17

MANUFACTURE OF EYE DROPS FOR LACHRYMAL STUDIES

There was a recent query about the production of $^{99}Tc^{m}$-colloid for use in lachrymal drainage studies, and whether this must be manufactured as a closed process. It seems that different units are employing different practices in relation to this. However, the advice is that, unless your unit is licenced (under a manufacturing specials licence) to allow aseptic fills, then the eye drops should be prepared and presented in either a vial or a syringe in order to maintain the closed system. It will then be up to the Nuclear Medicine Practitioners and Operators using the product to decide how best to safely administer the eye drops. There is a Specialist Pharmacy Services 'Yellow Cover' document on the preparation of eye drops that may provide further guidance on this topic.

CONTINGENCY PLANS IN RADIOPHARMACY

There are reports of radiopharmacy capacity issues from across the country. Some are the result of units having refurbishment work performed but in many cases it is due to staff shortages. As a result, many units are exploring contingency plans for the continued supply of tracer to the NM departments they usually supply. Such plans may include one or more of the following approaches:

- Sourcing radiopharmaceuticals from another licensed unit
- Using your own staff in another licensed or unlicensed unit

The issue of contingency planning has been discussed by the UKRG committee recently and, in relation to the second approach listed above, the group are currently writing a guidance document on the sharing of radiopharmacy facilities. Some areas of the UK are taking a regional approach to the development of contingency planning and this approach is advised if possible. That way, the scope of work, available spare capacity and contact details are known for all operating radiopharmacies within a region. Options for transport, which is often a limiting factor when sourcing externally, should also be considered as part of any plan.

REVISED UKRG GUIDANCE DOCUMENTS

The following two UKRG guidance documents are in the process of being revised:

- The Responsibilities of Chief Pharmacists for the Purchase, Receipt, Storage, Supply and Disposal of Radiopharmaceuticals
- Guidance for Introduction of a $^{68}Ge/^{68}Ga$ Generator and Labelling Service into Routine Clinical Practice

It is hoped that the updated versions will soon be available via the UKRG website.

ADVERTISING JOBS IN RADIOPHARMACY

When advertising job vacancies in your unit we encourage you to make use of the Radiopharmacy UK Email Discussion List. This is an excellent way to target your key audience.

If you haven't already joined this discussion group then you still can by following this link: www.jiscmail.ac.uk/radiopharmacyuk.

In order to be eligible you need to be employed by the NHS or the academic sector.

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 by individual companies.

Changes to Ecolab cleaning products
Ecolab are phasing out some of their cleaning products such as Klerocide B. Units using these products will need to consider alternative options and assess the impact of any changes made via a change control process. There has been some discussion around this issue on the Radiopharmacy UK Email Discussion Group (see previous section of the newsletter for details of how to join this group).

UPCOMING MEETINGS

UKRG Annual Workshop 2020
Friday 7th February 2020, Bournville, UK
Website: www.ukrg.org.uk

Understanding Microbiology for Aseptic Services
Thursday 23rd April 2020, Reading
Website

Aseptic Services for Managers
Tuesday 12th May 2020, Leeds
Website

From the Editor

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 where you can read the entire back-catalogue if you wish!

The next meeting of the UKRG Committee will be on 5th February 2020. If readers have any issues they wish to be discussed please raise them with your regional rep on the Committee 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.

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UKRG Annual Workshop, Bournville 2020

Continuing Professional Development in Radiopharmacy

Friday 7th February 2020

08:45 – 09:15 **Registration and coffee**

09:15 – 09:45

Microbiological monitoring overview

Rob Lowe
Lead Quality Assurance Specialist Pharmacist
Norwich

09:45 – 10:25

What every Radiopharmacy should know about transport – preferable before they have an ONR inspection!

Jilly Croasdale
Head of Radiopharmacy, City Hospital
Birmingham

10:25 – 10:55 Coffee and exhibition

10:55 – 11:15

HSE inspection and expectations update, including classification

Dudley Ibbett
Head of Nuclear Medicine
Derby

11:15 – 11:30

Audit of outcomes of radioiodine therapy. The story so far…

Shaun Johns
Trainee Clinical Scientist
Sandwell and West Birmingham

11:30 – 11:45

MDTs and dementia: how do they work

Dr Simon Hughes

11:45 – 12:00

Team Culture

Clint Waight
Head of Radiopharmacy, Royal Infirmary
Edinbourgh

12:00 – 12:30

Shifting emergency requirements from REPPIR into CDG / Emergency arrangements and scenarios

Martin Porter
Head of Operations
Sellafield

12:30 – 14:00 Lunch and exhibition

14:00 – 16:00

Workshop

Deviations / FMEA / RCA and responding to incidents

Lesley McAvoy
QA Specialist
Liverpool

Matthew Phythian
QA Technical Officer
Liverpool

16:00 – 16:15 **Summing up and closure**
Prof Neil Hartman
Swansea

U.K. Radiopharmacy Group