U.K. Radiopharmacy Group

NEWSLETTER
2013 – Q4
Edition

RADIOPHARMACY ERROR REPORTING

After a long gestation period UKRG has now launched a new on-line Radiopharmacy Error Reporting (ER) scheme which all members of the radiopharmacy community are encouraged to use.

A sample copy of the reporting form and its associated guidance notes are included as an Appendix to this Edition of the UKRG Newsletter.

The on-line version of the form will soon be available at this URL: www.ukrg.org.uk/errorform . [*Editor's note: UKRG has asked BNMS to place the Form on the website ASAP*]. The form is designed to be easy to use; it opens as a "form-fillable" PDF in Adobe Acrobat Reader. Many of the entries are selected from pull-down lists.

A major feature of the new ER system is that information submitted on-line will be collated by UKRG to produce an anonymous snapshot of radiopharmacy quality across the UK.

Once the form has been completed informants can:

- Print off a hard copy for their records;
- Save a en electronic copy for their records (when doing this you should use the "save as" function in Acrobat Reader and provide a local unique file name for the event; if you simply "save" you will overwrite the template report form and will then need to download another copy for subsequent events)
- Submit electronically by e-mail a copy of the data fields from the form to the dedicated UKRG reporting mailbox (errors@ukrg.org.uk); these data fields will populate the UKRG ER database, allowing detailed analysis and trending of errors [*Editor's note: this reporting mailbox is already live, and can be used by those who save a copy of the Form from this Newsletter*].

Readers are encouraged to adopt the new ER form into their local Radiopharmaceutical Quality System and submit details of errors occurring to the UKRG. A summary of submissions from sites piloting the Form and made before 31st December 2013 will be presented at the UKRG Annual Workshop at Bournville in January 2014, and a report included in the 2014-Q1 edition of the Newsletter.

"SHARPS" REGULATIONS

UKRG guidance on the re-capping of needles in radiopharmacy and nuclear medicine has now been published and can be downloaded from the UKRG website at this URL:
http://www.bnms.org.uk/images/Recapping_needles_UKRG_guidance_v5_UKRG_format.pdf

REGULATORY ISSUES

MHRA Guidance on EU GMP

In October 2013 the MHRA issued a "Q&A Document" giving up-to-date guidance on how it interprets EU GMP as it relates to holders of a Manufacturer's "Specials" Licence. The guidance has been developed to ensure consistency during routine Good Manufacturing Practice (GMP) inspections and to ensure MS license holders are aware of MHRA expectations in this complicated area. It is planned as a 'living' document which will be updated as required. **A period of 6 months (up to 1 April 2014) will be given for MS Licence holders to become familiar with this document and implement any changes to their operations and quality systems which may be required.** The document is commended to Newsletter readers. It can be found at this URL:
http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con326474.pdf

Recent MHRA inspections

During 2013-Q3 a new NHS PET facility had received a GMP Inspection. A number of Quality System deficiencies had been identified at the inspection. These included:

- No daily magnahelic checks recorded
- No recorded SPC checks
- No visible inspection at Batch release

The site also produced products for both commercial use and NHS use. It was heavily involved in research activities. One design fault identified was that the two hot cells were not located together and that the filtration was being carried out in a Grade C environment, after which the product was stored for long periods. Guidance for aseptic manufacture for research units is to be produced as a result of problems found.

"QUALITY ASSURANCE OF ASEPTIC PREPARATION SERVICES"

The reference publication, the "Quality Assurance of Aseptic Preparation Services", published by the National PQAC, is being revised under Alison Beaney's editorship. This is essential reading for unlicensed radiopharmacy units operating under Section 10 exemption. Watch this space for details of a publication date.

BNMS SPRING MEETING 2014

As we go to press, UKRG is working hard preparing an exciting Radiopharmaceutical Science session for the 2014 BNMS Spring Meeting to be held in Harrogate, 11th-14th May 2014.

The session will include invited presentations, which may include the following topics:

- Agents for SLN studies
- Medicines management: what does it mean for radiopharmaceuticals
- How to manage an RCP failure

Readers are encouraged to submit abstracts for presentations to be included in this session; the abstract submission closing date is 6th January 2014.

CENTRES ANNOUNCED FOR COMMISSIONING OF SIRT

In November 2013 NHS England announced details of the hospitals chosen to take part in new £4.8 million initiative, aimed at increasing access to specialist radiotherapy services. The 10 centres will provide Selective Internal Radiotherapy (SIRT) to around 220 patients a year as part of a time-limited programme called 'Commissioning through Evaluation'.

The successful centres are:

Newcastle-upon-Tyne Hospitals NHSFT
The Christie NHSFT
Leeds Teaching Hospitals NHSFT
Oxford University Hospitals NHSFT
University Hospital Southampton NHSFT
University Hospitals Birmingham NHSFT
Nottingham University Hospitals NHSFT
Cambridge University Hospitals NHSFT
Kings College Hospital NHSFT
The Royal Free London NHSFT

SIRT, which is a form of radiotherapy used in the treatment of cancerous tumours in the liver, is not routinely funded by the NHS as the current evidence base does not yet demonstrate sufficient clinical and cost effectiveness for its routine use.

Commissioning through Evaluation will enable SIRT to be funded within defined parameters, in a relatively small number of centres, and within an explicit evaluation programme. It is anticipated that the programme will be funded for between 1-3 years.

This approach provides an opportunity for patients, who are deemed clinically suitable, to access SIRT – a treatment which shows significant promise in terms of improving quality of life – but is not accessible through a formal research trial.

Dr Adrian Crellin, Chair of NHS England's SIRT Commissioning through Evaluation Steering Group, said:

"This is a very exciting development for those patients who can potentially benefit from treatment with SIRT, and for those clinicians who wish to contribute to the growing evidence base supporting this treatment.

"NHS England is committed to expanding access to all forms of specialist radiotherapy, and we await the outcome of this innovative commissioning programme with some anticipation, as is it will help us determine how best to deliver these important, and life-saving, services to patients in the future".

INDUSTRY NEWS

UKRG Disclaimer: 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.

GE Healthcare Customer Portal

GE Healthcare wishes to remind Readers that it is working towards a paper-free communications process and has a launched a "Customer Portal" giving GE customers access to a wide range of important information. Customers can register to use the Portal by completing an online form at the following URL: http://supportcentral.ge.com/esurvey/takesurvey.asp?p=17778&d=3771689 (registration instructions will be sent once the form is submitted). Information currently on the Portal includes, *inter alia*: customer letters; current SPCs; current PILs (a limited range at present); Technologist Guides (currently just for DaTSCAN® and SeHCAT); a DaTSCAN® reporting guide; and a form for reporting adverse events to GE Healthcare.

A recent customer letter on the Portal (late November 2013) indicates that GE Healthcare anticipate "business as usual" for existing Drytec generator customers, in spite of the current Mo99 supply problems, but it was unable to take any new Drytec business or increased volume at that time. Updates are being notified via the Portal and also sent to the BNMS. Not withstanding this, UKRG understands that GE Healthcare is reviewing the delivery/reference date regime for the Drytec generators (currently only available on two days per week). [*Editor's note: Hopefully information about this will be available in a future edition of the Newsletter*].

GE Healthcare has also announced changes to the packaging and courier arrangements for some of their products requiring "cold-chain" delivery. The products concerned are: Ceretec™, Stabilised Ceretec™, Myoview™, Nanocoll, Optison™, Hexvix® and Rapiscan®. From 2nd December 2013 these products will be shipped in smaller packages without "passive temperature control" (no expanded polystyrene box or "freeze packs"); as a consequence there can only be delivered during "office hours" in order that they can be "refrigerated immediately on arrival".

Imaging Equipment Ltd launch generic albumin nanocolloid (Rotop "Nanotop") in the UK.

Imaging Equipment Limited are pleased to announce that they will be distributing a newly licensed Radiocolloid called "Nanotop" from ROTOP which has been available for sale in several European countries for two years, but has only recently received a UK product licence through a mutual recognition procedure (*). The human albumin colloidal particles are the same qualitative and quantitative composition as Nanocoll (GE, Amersham) with 95% of particles being ≤ 80 nm; less than 5% free 99mTc after radiolabelling, and a pH of 7 - 8. Importantly, the mean particle size is highly consistent and varies by only ± 1.3 nm over the last 22 batches manufactured by ROTOP. The manufacturing process is the same for both products utilising colloid formation through a process of thermal denaturation. The consistency between both products enables surgeons, nuclear medicine specialists and radiopharmacists to switch between products with minimal disruption. The obvious advantage of a product which is identical and third to market is that the pricing will be competitive and should result in significant savings to the NHS.

[(*) *Editor's note: details of the EMEA ruling on Nanotop are available this URL:* http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Nanotop_and_associated_names/human_referral_000358.jsp&mid=WC0b01ac05805c516f . *Also, there will be a short presentation about Nanotop at the Bournville Workshop on 17th Jan 2014.*]

Bartec Technologies to supply Nuclear Medicine software systems in the UK

Bartec Technologies Ltd is pleased to announce that it has entered into an agreement to be UK and Ireland agents for ec² Software Solutions.

ec² Software Solutions is the leading provider of nuclear medicine software in the U.S. with an installed customer base of over 5000 locations including hospitals, clinics, radiopharmacies and cyclotron facilities. ec² Software Solutions have designed a range of products to improve Radio-pharmacy Management, Patient Management, Health Physics, Statistical Analysis and Accreditation.

For more information please mail sales@bartectechnologies.com or call Mike Bewick on +44 127620842

[Editor's note: some information on these products can be found at this URL: http://www.ec2software.com/]

UPCOMING MEETINGS

2014

UKRG Annual Workshop: Continuing Professional Development in Radiopharmacy
Date: 17th January 2014, Bournville, UK
Website: www.ukrg.org

European Compliance Academy: Radiopharmaceuticals – Quality, Safety and GMP Requirements
5 Feb, Vienna, Austria
Website:
http://www.gmp-compliance.org/eseminar_8433_Radiopharmaceuticals%20%E2%80%93%20Quality%2C%20Safety%20and%20GMP%20Requirements.html

ESRR'14 European Symposium on Radiopharmacy and Radiopharmaceuticals
24-27 April, Pamplona, Spain
http://esrr14.eanm.org

ANZSNM Annual Meeting 2014
25 April, Adelaide, Australia
Website:
http://www.anzsnm2014.com.au/index.html

BNMS Spring Meeting
11–14 May 2014, Harrogate, UK
Website: www.bnms.org.uk

3rd PET/MR and SPECT/MR Conference: Paradigms for Combined Modalities in Molecular Imaging
19-21 May 2014, Kos Island, Greece
Website: http://www.pet-mri.eu/psmr14.html

SNMMI Annual Meeting 2014
7-11 June, St Louis, Missouri
Website:
http://interactive.snm.org/index.cfm?PageID=13055&navItemNumber=581

11th Congress World Federation of Nuclear Medicine and Biology (WFNMB)
27-31 Aug, Mexico
www.wfnmb.org

www.ukrg.org.uk

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Appendix 1 - A copy of the Error Reporting form is shown below. A "live" copy is attached at the end of the Newsletter (page 7): You can save a blank copy to your local computer (which will include a copy of the Newsletter!); you can also complete a copy with details of an error and then save and/or print a copy locally, and e-mail a copy to the UKRG, by clicking on the appropriate button. There is also a facility to send feedback to UKRG on the use of the form. In due course a copy of the form will be available from the UKRG Website.

RADIOPHARMACY ERROR / NEAR MISS REPORTING FORM

Local report number:		Date error was made:		Reported by (initials):	
Radiopharmacy product description:		Final Radiopharmacy product batch number:		Final product expiry:	
Starting material(s) description:		Starting material(s) lot / batch number(s):		Starting material(s) expiry:	

DETAILS OF ERROR:

Product category:		Error type:	

DETAILS OF STAFF INVOLVED IN THE ERROR:

Who made the error?	Staff group to which this person belongs:
When was the error detected?	

DETAILS OF INVESTIGATION:

ROOT CAUSE OF THE ERROR (please record details of the root cause of the error identified from investigation):

RADIOPHARMACY OUTCOME CLASSIFICATION:

Patient outcome:	GMP outcome:

CORRECTIVE ACTION:

PREVENTATIVE ACTION:!

DATE / TIME AT WHICH QC or ACCOUNTABLE PHARMACIST WAS INFORMED:	
INVESTIGATION COMPLETED BY:	

RELATED DOCUMENT NUMBERS:

NOTES:

1 Use a separate form for each incident. Attach copies of all relevant documentation to this form and keep in the local error reports file.

2 **When the form has been completed, please click on "E-mail Form" button** to e-mail a copy of the form to the UK Radiopharmacy Group

3 PRODUCT CATEGORIES:

A $^{99}Tc^{m}$ compounded kit
B Other compounded kit (*e.g.* ^{111}In)
C Finished product (*e.g.* ^{123}I *m*IBG)
D Blood labelling product
E Batch prepared product (*e.g.* ^{51}Cr EDTA)
F Other radioactive products (*e.g.* therapy)
G Other non-active products

4 ERROR TYPE DEFINITIONS:

A Incorrect request
B Incorrect transcription
C Radioactive patient dose calculation error
D Radioactive worksheet calculation error
E Incorrect assembly/preparation/radiolabelling
F Incorrect radiopharmaceutical
G Incorrect dose measure (human error)
H Incorrect dose measure (machine error)
I Incorrect diluent
J Incorrect final volume
K Labelling (paper) error
L Radiolabelling error (radiochemical purity)
M Incorrect expiry date
N Incorrect container (*e.g.* syringe, vial)
O Packaging error (*e.g.* Type A or excepted)
P Dispatch error (*e.g.* wipe test or transport certificate)
Q Other (please give details)

5 WHO MADE THE ERROR CATEGORIES:

A Person taking order
B Person preparing paperwork in advance
C Person preparing / (paper) labelling vials
D Manufacturer
E Person checking products
F Person releasing products
G Person transporting products

6 STAFF GROUP CATEGORIES:

A Pharmacist / Radiopharmaceutical Scientist
B Technologist / technician
C ATO / SATO
D Radiographer
E Student / pre-registration pharmacist
F Nurse
G Doctor
H Medical Physicist / Clinical Scientist
I Driver
J Other

7 WHEN WAS ERROR DETECTED CATEGORIES:

A By self when checking
B First check - in assembly area
C Operator check - in preparation area
D During assembly /preparation / radiolabelling
E During calibration
F During labelling (paper)
G Final check PRIOR to release
H At release stage
I On receipt
J In clinical area prior to administration
K In clinical area during or after administration

8 INVESTIGATION – WHY DID THIS HAPPEN?

At first sight, many errors will be due to staff error although the process itself should be examined to see whether there are other contributory factors. The '5 Why' technique is one approach which may be of use, as this prompts the investigator to look deeper into the causes of errors. Other contributing factors may be the facility layout, the process workflow, the type of staff being used for roles, the adequacy of any computer system, low staffing levels, high workload, poor segregation of different parts of the process, distractions and interruptions.

9 RADIOPHARMACY OUTCOME CLASSIFICATIONS:

	OUTCOME	DESCRIPTION	PATIENT-RELATED EXAMPLE	GMP-RELATED EXAMPLE
A	NONE	No obvious harm.	Administered activity significantly lower than normal (*e.g.* ≤25%) but no additional administration required.	
B	MINOR	Non-permanent harm (≤ 1 month) to patient OR minor GMP documentation failure with no patient impact	Patient appointment delayed but still same day	Disruption of audit trail *e.g.* incorrect batch number detected before product leaves department.
C	MODERATE	Semi-permanent harm (≤ 1 year) to patient OR GMP failure with no patient impact	Patient appointment delayed – appointment rebooked for another day	Significant error on paperwork *e.g.* incorrect activity on label, but correct activity administered to patient.
D	MAJOR	Permanent harm to patient OR major GMP failure with an impact on patient	Patient received significantly greater radiation dose than expected, leading to increased likelihood of leukaemia or other cancer.	Significant GMP failure resulting in administration of incorrect product
E	CATASTROPHIC	Possible death	Therapy dose administered to wrong patient leading to acute radiation damage (*e.g.* kidney failure); administration of blood product to wrong patient; unnoticed administration of diagnostic dose to wrong patient leading to misdiagnosis and inappropriate, life-threatening surgical or therapeutic intervention.	Significant GMP failure resulting in administration of incorrect product.

RADIOPHARMACY ERROR / NEAR MISS REPORTING FORM

Local report number:	Date error was made:	Reported by (initials):
Radiopharmacy product description:	Final Radiopharmacy product batch number:	Final product expiry:
Starting material(s) description:	Starting material(s) lot / batch number(s):	Starting material(s) expiry:

DETAILS OF ERROR:

Product category:	Error type:

DETAILS OF STAFF INVOLVED IN THE ERROR:

Who made the error?	Staff group to which this person belongs:
When was the error detected?	

DETAILS OF INVESTIGATION:

ROOT CAUSE OF THE ERROR (please record details of the root cause of the error identified from investigation):

RADIOPHARMACY OUTCOME CLASSIFICATION:

Patient outcome: Click to access NPSA risk rating guide	**GMP outcome:** Click to access MHRA deficiency classification

CORRECTIVE ACTION:

PREVENTATIVE ACTION:!

DATE / TIME AT WHICH QC or ACCOUNTABLE PHARMACIST WAS INFORMED:	
INVESTIGATION COMPLETED BY:	

RELATED DOCUMENT NUMBERS:

Save form | Print Form | E-mail Form | Send feedback