PIC/S Guide to good practices for preparation of medicinal products in pharmacies
(PIC/S Document PE 010-1, Draft 2, dated 23 August 2006)

Feedback form for consultation amongst associations

⇨ Please use this form only for any comments.

⇨ Please submit your comments no later than 30 March 2007 to info@picscheme.org.

Thank you very much in advance!

1. Association submitting this feedback

Name and address of association:
The Royal Pharmaceutical Society of Great Britain
1 Lambeth High Street
London
SE1 7JN

Country:
England

Contact person:
- Name: Robert Clayton
- Telephone number: 0207 572 2207
- Fax number: 0207 572 2501
- E-mail address: Robert.clayton@rpsgb.org
- Website: www.rpsgb.org

Date of the submission of the feedback: 30 March 2007

30 March 2007

PRACTICE AND QUALITY
IMPROVEMENT DIRECTORATE
Telephone: 020 7572 2207
Facsimile: 020 7572 2501
e-mail: robert.clayton@rpsgb.org

info@picscheme.org.

Dear Sir/Madam,

I write on behalf of the Royal Pharmaceutical Society of Great Britain to respond to the above consultation.

The Royal Pharmaceutical Society of Great Britain is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, which is expected to become statutory under anticipated legislation.

The primary objectives of the Society are to lead, regulate, develop and represent the profession of pharmacy.

The Society leads and supports the development of the profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

The Society has responsibility for a wide range of functions that combine to assure competence and fitness to practise. These include controlled entry into the profession, education, registration, setting and enforcing professional standards, promoting good practice, providing support for improvement, dealing with poor performance, dealing with misconduct and removal from the register.

The Society requests that the following collated comments from individual pharmacists based in the hospital pharmacy service are taken into consideration:

The implications with this document will certain increase workload pressures:-

- Extemporaneous preparation requires that starting materials are approved with appropriate documentation. At present we have a worksheet that lists starting materials but this is not appropriate if we use unlicensed materials e.g. suspending agents.
- Section 4.4.2 states the need for pharmaceutical assessment of the product. At present we have not been required to do this, although we do cover some aspects.
- Section 4.4.3 - a product review is required. There is a need to establish although the all Wales QC/A group are looking at a more general review of processes and facility.
- Section 5.4 Product risk assessment for each product. However, this should be encompassed within the change control procedure as we will have to risk assess each critical step. We do it although like most units we do not always document it.

The section dealing with sterile and non sterile preparation standards (Annex 1 Section 2) has many issues:

- Point 24: Grade D areas require a protective suit. At present in the prep room area we do not do this although we easily achieve grade D if not C. This would require an initial change on entry to the prep room and hence an extra cost(double the amount of clean room coats) as there would be a second stage change in the change room.
- Point 26: The cytotoxic room and isolators require grade C clothing and face mask. At present we do not do this and we would need to wear face masks but more importantly, a single or two-piece trouser suit, needs to be worn. This would bear an additional cost as we only wear a coverall coat which only complies with grade D positive pressure isolators.
- Point 28: Currently mop heads are changed every two to four weeks depending on condition. This does not comply as these need to be disposal or sterilised each cleaning session. Clearly, this would bear greater financial pressures as consumables would greatly increase. The environmental monitoring has not picked up any major issues as we could argue but it is not compliant.

Section 5 Quality control:

- Testing (chemical) would need to be carried out on products greater than 24hours for stock. This would involve probably UV methods but need to be validated beforehand resulting in additional QC work.
- Microbiological testing would be exempt providing the process validation are up to date reflecting any potential changes.
- Products greater than one month need to be tested. We comply with microbiological but would need to at least identity tests on products. However, with morphine solutions of different strength it would be wise to use a UV method.
- Point 78: Methods should be stability indicating. This can only be carried out with HPLC and only 2 sites in Wales can do this work.

Section 6 Environmental monitoring This would require significant resources to carry out the minimum level of requirements

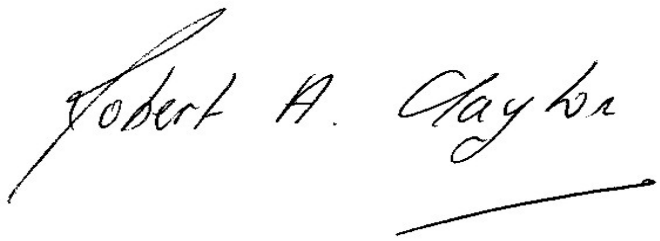
- Weekly Surface samples. At present done monthly (RGH) .Current standard is weekly(National QA/C). In view of more regular active air and particles we currently can justify but next inspection may not.

- Active air sampling weekly. At present done monthly (RGH). Current standard is 3-monthly (National QA/C)
- These requirement would require additional staff and probably the purchase of more air samplers to achieve this.
- Reduced monitoring may be acceptable, where justified by a documented risk assessment

We hope these comments are helpful.

Thank you for consulting the Society.

Yours sincerely,



Robert Clayton
Head of Practice