Guidelines for the Blood Transfusion Services

7.1.2: Irradiated components

http://aws-lon-jpac.targetservers.uk/red-book/chapter-7/7-1/7-1-2

7.1.2: Irradiated components

- For the whole of this section X-irradiation may be regarded as equivalent to gamma irradiation. Times when irradiation should be undertaken and the permitted post-irradiation storage times are the same, as are the required labelling and dosing (recommended minimum dose achieved in the irradiation field is 25 Gy, with no part receiving >50 Gy) (±10% at 95% confidence interval).

- Note that the X-ray equipment should be dose-mapped prior to release from the factory and at installation, and the manufacturers recommend routine dosimetry at 6-monthly intervals (gamma-irradiation equipment requires annual dosimetry). A radiation-sensitive label specifically for use with X-irradiation is available.

- It is not necessary to irradiate the following components:
  - cryopreserved red cells after washing
  - plasma components that have been frozen below –25°C.

- For more information, refer to the British Society for Haematology (BSH) Guidelines on the Use of Irradiated Blood Components.[2]

- Irradiated components not used for the intended recipient can safely be used for recipients who do not require irradiated components provided the other requirements of Chapters 6 and 7 have been satisfied. However, any reduction in shelf life resulting from the irradiation process must be observed.

- Irradiated components should conform to their appropriate specification previously given in this chapter. In addition, the guidelines shown below should be observed.

7.1.2.1: Description

Irradiated components are components that have been irradiated by a validated procedure.

7.1.2.2: Technical information

- Other than for use in intrauterine transfusion, exchange transfusion, or large-volume transfusion of neonates, red cells can be irradiated at any time up to 14 days after collection.

- Platelets can be irradiated at any stage in their storage.

- Granulocytes should be irradiated as soon as possible after production.

- Liquid plasma can be irradiated at any stage in its storage. (Liquid plasma refers to plasma that has not been frozen and has been stored throughout its shelf life at 4 ±2°C).

- For red cells, platelets, liquid plasma and granulocytes the recommended minimum dose achieved in the irradiation field is 25 Gy, with no part receiving >50 Gy (±10% at 95% confidence interval).

- Laboratories performing irradiation of blood components must work to a clearly defined specification and are strongly recommended to work closely with a medical physicist. The defined irradiation procedure must be validated and there must be regular monitoring of the blood component dosimetry and the laboratory equipment. Provided the blood dosimetry uncertainty of measurement used by blood establishments is equal to or less than the uncertainty as it was measured in the original study data (±10%),[3] there is no clinical indication to include the uncertainty of measurement within routine mapping to confirm ongoing specification compliance.

- It is recommended that irradiation of blood components is carried out using dedicated blood irradiation machines. If radiotherapy machines are used, equivalent protocols should be developed.

- Appropriate radiation-sensitive labels should be used as an aid to differentiate irradiated from non-irradiated components. However, it may not be necessary to attach a radiation-sensitive label to every component pack, provided that the irradiation procedure follows a validated, documented and well-controlled system of work that is integrated with the component labelling and release mechanism and permits retrospective audit of each stage of the irradiation process.

- There should be a permanent record of all units irradiated. This should include details of irradiation batch and donation numbers, component type, the site of irradiation, when irradiation was performed and by whom.

7.1.2.3: Labelling

- Irradiated components must be identified by the applied labelling and include any reduction in shelf life.

- Labels which are sensitive to irradiation and undergo a visual change are available and are considered a useful indicator of exposure to irradiation. The dose at which the label changes to indicate irradiated status must be marked on the label. It must be remembered that such labels simply reflect that the unit has been exposed to radiation and their use does not replace the need for regular and precise dosimetry nor carefully controlled working procedures.

7.1.2.4: Storage

For general guidelines, see section 6.7.

- Red cell components, other than washed red cells and those for intrauterine transfusion, exchange transfusion, or largevolume transfusion of neonates and infants can be irradiated at any time up to 14 days after collection and stored for up to 14 days thereafter, provided the other requirements of this section are adhered to.

- Washed red cells can be irradiated at any time up to 14 days after collection. Irradiation should take place after washing. Following irradiation washed red cells that are suspended in a validated additive solution should be transfused as soon as possible and no later than 5 days after irradiation if irradiated on the day of washing, or 48 hours if irradiated after the day of washing.