RECORDING OF ACQUISITIONS AND STOCK OF RADIOACTIVE SUBSTANCES, AND RECORDS OF THE DISPOSAL OF RADIOACTIVE WASTE

1. Introduction

Departments have in place record systems, reflected in their Local Rules and other documentation, which are appropriate to the particular ways in which radioactive substances are used in their Departments. Part of the purpose of the programme of audits by the University's Radiation Officer and Radiation Protection Advisers, is to assess the adequacy of these record systems. To ensure compliance with the relevant legislation such as IRR1999 and EPR 2010, a minimum standard of documentation must be maintained, as described in the information below, together with the attached examples of forms. There are electronic/computer based record keeping systems available which can be used to keep records in a consistent way across an organisation. Currently however, the advice of the RPAs and the Safety Office is that departments continue to manage records relating to radioactive substances in a largely 'paper based' manner, but, if desired, with the use of local spreadsheet summary records of stock and disposal data.

2. Record Keeping

The essential elements of the recording system are outlined below. Wherever possible, the use of the standard forms provided as examples, is recommended to ensure compliance. Alternative, electronic systems, if used must incorporate the advice below

3. The Central Departmental Record (or 'Ledger')

Each department that is permitted to keep, use or dispose of radioactive substances, must keep a simple ledger, recording all orders placed, deliveries received and, eventually, an annotation to indicate the eventful disposal or otherwise transfer of all of the material from the department.

It is possible that this could be a computer ledger, provide there is also a currently updated, printed and bound hardcopy used for quick reference by the RPS, and visiting Environment Agency Inspectors. Mistakes in entering data into the ledger should be clearly struck through, and the correct information then appended together with a signature – do not 'tipp-ex' out information on any records that are kept to demonstrate compliance with the Legislation.

The ledger should have columns to indicate:

- **Ordering details** (Ordering date, departmental order number, substances, radionuclide, quantity, person/group requesting order)
- **Details of receipt by Department** (date delivered, manufacturers batch number, radiochemical reference date, unique identifying number (See Section 4), signature for receipt by user, details of normal storage location.
- **Date of final disposal**

The ledger should be updated first at the point when an order is placed. It is very important to identify orders that are placed but never received. There has been recent first hand experience of how important it is to be able to show documentation right back to the placing of an order when things go wrong.

When pots of radioactive substances are fully used and discarded, the ledger must be annotated to reflect this. It is acknowledged that with *multiple* aliquots of some stocks of long half life (such as C14) this can be rather difficult to ensure in practice. This 'ledger approach' can help Departments with their internal auditing of stock and

highlights the existence of samples which are too old to be of any use and therefore require disposal. A standard inspection technique used by the Environment Agency (and the University Safety Office), is to review the ledger, looking for 'old' stocks', and then to ask to see further documentation, the actual stocks, and to visit the area in which they are used and stored.

4. The Unique Identifying Number

Departments are left to devise their own systems of numbering each incoming stock ('pot') uniquely, but those responsible must be made aware that the following systems that have been noted during audits are **not** acceptable:

- Use of the Department's order number alone as a pot identifier. (Single orders can occasionally involve more than one pot and the system must be set up to identify each item within a delivery).
- The manufacturer's batch number as an identifier. (Manufacturers prepare large numbers of stock items from one batch, especially with longer half life radionuclides).

A simple system that works well in one department is an alphanumeric system composed of the initials of the user group or individual and a running number e.g. MV1, DP2, LY3 might be a series of stock items for different groups in the Safety Office. This system has the advantage of immediately identifying the owner and being fairly simple to transcribe onto the actual stock containers.

Clear instructions must be issued by the Department as to whose duty it is to generate the unique identifier and to write it on to the stock pot and onto all related records. In practice this is likely to be the RPS who has the designated task for working with 'stores' and who liaises with them on the days that items are received. However it does not have to be the RPS, provided it is the person who oversees receipt and onward distribution of incoming stocks items, and is fully aware of the systems for control of radioactive substances withi9n the department.

5. Stock Cards

(The 'stock pot card' or "dispensing and use card" is the record card or sheet, for a single stock item, that is affixed to fridges or freezers (or kept nearby in a dedicated file). Under the current system it should be a hard copy record, instantly available to authorised users of the radioactive substance in question.

Enclosed with this guidance document are two examples of stock record cards for use by Departments. It is appreciated that some Departments have devised their own variations of forms for stock record keeping, but, these examples must be seen as the minimum standard acceptable. The aim is that the standard formats for the content of record cards must be acceptable to all Departments. If more dispenses are envisaged than there is room for on the form, the form should be 'backed' providing spaces overleaf for recording the required information. The second, alternative, format given here, may be more useful if multiple dispenses (aliquots) of longer half life items are envisaged, particularly if these are made at time of receipt of the item into the department.

If Departments consider it is necessary to continue to use forms developed within the Department, these should be examined to ensure that that they contain the following essential information:

- Headings showing: definition of the substance, the radionuclide, initial volume, radioactivity reference date, person (and group) responsible for the

sample, storage place when not in use, and the unique identifying number. The headings must also include the "nominal quantity of radionuclide, i.e. the amount ordered, which we currently use for all dispensing calculations, and the "activity on receipt" that is the actual received activity, based on the supplied 'activity date', allowing for users to be certain of 'actual' activity prior/post the activity reference date. The "activity on receipt" value is included for the purpose of demonstrating compliance with the Environment Agency Permits, and for users experimental needs – it is not generally used in our current record keeping system, as, of course, this activity/unit volume will continue to decline, making re-calculations necessary each time an aliquot is withdrawn.

- The table must include columns for date, volume withdrawn, activity withdrawn, signature of person withdrawing aliquot, activity disposed via drains, activity disposed as solid waste, activity disposed by other means and the routes of these disposals.
- All radioactive substances must be recorded in SI (MBq) units.
- The stock sheet must carry clear instructions that it must be **returned to the RPS** as soon as the stock pot is empty, all material has been disposed, and all aliquots used up.

Responsibility for Stock Cards

Clear instructions should be issued as to whose responsibility it is to complete the stock card before it over handing to the user, (for example, stores manager, RPS or other – see section four, above)

6. Transfers of Materials to Other Users

The situation sometimes arises whereby it is convenient to transfer an aliquot to a colleague outside the Department. Although this practice is not encouraged, it is appreciated that collaboration between groups sometimes makes this unavoidable. Provided other matters such as the Transport Regulations, can be taken care of, there is essentially no problem in this taking place. The stock sheet should show this as e.g. "transferred to J Bloggs, Department of X" in the disposal columns.

7. Received Gifts

The corollary of the above is that from time to time, materials will be received that have not been processed through the normal ordering system. Their receipt must be recorded in the ledger and marked as e.g. "Gift from X of Department Z" in the ordering detail columns, but otherwise treated exactly as any other received sample. It is also recognised that samples are, from time to time, received as free gifts from commercial suppliers – the same control measures apply to these samples and although they have not been acquired against an order, it is very important that they are recorded in the ledger and treated in the same way as any ordered sample.

Occasionally there may be need for specific exceptions to the above guidelines, for instance for a departments embedded within another employers building – but any exception to the 'standard' arrangements must be agreed between the RPAs/RPOs of both organisations, and with the respective RPSs before any customised record systems are introduced.

8. Aliquotted Samples

Certain labelled materials e.g. 35-S methionine, 14-C labelled marker proteins, are routinely aliquotted on receipt to avoid repeated freezing and thawing. The aliquots must be stored in a labelled container bearing the radiation trefoil (for example a section of adhesive 'radioactive tape), details of the material contained, the aliquot

size and most importantly, the unique identifying number. It is appreciated that there are practical difficulties in labelling very small aliquot tubes, but a minimum requirement is that they are sequentially numbered within the labelled container, and proper records kept. The aliquot size should be noted on the stock sheet, or subsidiary stock sheets as noted above. Removal of each aliquot from the container should be recorded as a withdrawal on the relevant stock sheet in the normal way and the anticipated disposal details completed.

9. Reagents prepared from Radioactive Substances

The bulk of the radioactive material purchased by the University is in the form of ready labelled compounds which are used and subsequently disposed as waste. However, there are situations where material is purchased for the purpose of preparing the working reagent. Examples are the use of iodine-125 for labelling antibodies and protein ligands, and tritiated water for preparing labelled reagents. This creates a situation whereby the record card for the original pot, indicates that a significant amount, and eventually the total contents, are shown as withdrawn, but the radionuclide has not disappeared from the Department. To maintain an adequate record of material held by a department, again it is necessary to create a secondary stock sheet to record the holding and disposal of these prepared reagents where it is expected that they will be used on multiple occasions over a period of time. Typical examples would be a batch of iodine-125 labelled protein A which might be used for a series of Western blots or binding assays over a 3 month period, or a tritiated drug which might be used in binding assays for the next year. The material should be given a new unique identifier preferably derived from the identifier of the material used to prepare it e.g. CB23/A, CB23/B might be two iodine-125 labelled antibodies prepared from iodine-125 pot CB23.

10. Retaining Records (Ledgers and Stock Cards)

It should be noted that the stock sheets are the **primary** records of stock and must be retained. Current guidance from the Environment Agency requires that records are retained for at least 10 years after the sample has been completely used and disposed but it is our view that it is prudent, subject to available space to keep them indefinitely or at least for the life of a Department unless otherwise agreed with a visiting EA Inspector. We have recently inherited problems that relate to purchases made over 25 years ago that would have been easier to resolve, or possibly would never have arisen, if the stock sheets were still on file! The same approach should be made in respect of records sent to the Safety Office (monthly returns) and the copies of forms used for recording information when transferring radioactive waste to the Safety Office collection system (the ‘transport document’).

For the above reason, it is important that the primary record for pots no longer in use, i.e. those used and disposed, are retained centrally by, or on behalf of, the lead or senior RPS (archiving these records within research groups can be risky as individual groups move to new laboratories, leave the University and this provide opportunities for their stock sheets to be lost or destroyed).

If a Department ceases to use radioactive substances and accordingly ceases to have an appointed RPS, the records should be passed on to a responsible person (Head of Department, Departmental Secretary etc.) The Department even though no longer using radioactive substances, will remain on the University’s Permits for some time and will still be liable to audit by the Environment Agency. The information will also be needed when the need to ‘decommission’ the building takes place, this prior to the Environment Agency agreeing to remove reference to the building on the Certificates.

If a Department is permanently closed, the records should be passed to the Safety Office for safe keeping for the above reasons. Advice on decommissioning is available from the Safety Office

11. Records of accumulation of solid and scintillation waste, and sink disposal records

In addition to the stock card, a running record of radioactive waste disposal must be maintained adjacent to each designated disposal sink. A record sheet must be also be maintained for each container designed to hold solid or scintillation waste within a laboratory prior to transfer to the Department's main radioactive waste store. These record sheets must be kept up to date. That is, **on the day** that a user disposes some radioactive waste to these locations, an appropriate entry must be made on the form. It is not essential to continue the "unique identifying number" system onto the record sheets kept at designated sinks or on solid waste containers. Depending on the local arrangements of the Department, these sheets, when completed, should retained in the Laboratory or returned to the RPS or other person within the Department responsible for the organisation of radioactive waste disposal.

It may appear that the above paragraph introduces a degree of "double recording" and may be seen as introducing unnecessary work for the users. However, the Certificates issued under the Environmental Permitting Regulations 2010 (EPR10), are quite specific in requiring that a clear and legible record is made **on the day** of accumulations or disposals of radioactive waste. The records should be easy to access and interpret, without the need to refer to a series of stock cards or similar in order to determine the amounts of waste accumulated or disposed within a laboratory.