RPR CRITERIA AND FORMATS

PURPOSE

This procedure establishes design criteria and standard formats for detailed procedures and records required for effective operations, communications and management of the University's radiation protection program. Specific attention is given to generation, authentication, linkage, storage and recovery of records related to the radiation protection program.

POLICY

Procedures and records developed, used and maintained for the radiation protection program shall conform to standard procedures and policies established by the University of Utah. Procedures shall be sufficiently detailed and comprehensive to assure consistent and unambiguous communication of instructions. Records shall be complete, consistent and in conformance with standard procedures to assure that all data can be recovered, verified, interpreted and legally accepted. Records shall be retained in a location protected against damage from natural or manmade causes for the length of time required by law, regulation or University policy.

DEFINITIONS

Database - a comprehensive, relational compilation of data stored on the Radiological Health Department's computer network. The database is a management tool; it is not considered to be a repository of primary records.

Field - a basic unit of information that is part of a record. The contents of a field may be data, a code or a pointer.

File - a group of similar records covering a specific category of information.

Form - a prepared outline, often preprinted, used to acquire or retain data for a radiation record.

Key - the datum uniquely identifying one particular record in a file. In an electronic record, the datum is contained in a "key field". The key may be unique data, e.g. a social security number, or simply a sequential record number, but must positively identify one, and only one, record in the file.

Linkage - the cross-referencing of records in one file to other records contained in the same file or records in another file. Linkage is accomplished by fields containing pointers. Links form the basis for relational databases, avoiding unnecessary redundancy.

Ministerial changes - changes in format or wording of procedures or records that do not conflict with any regulatory requirement or license condition, and that do not diminish or adversely affect radiation protection.

Pointer - information in a field of a record that links that record to another in the same or a different file.

Radiation procedure - a detailed procedure issued by the RSO as an instruction or guideline for users of radiation sources to supplement the *Radiation Safety Policy Manual*, or to define procedures affecting the University's radiation protection program and its documentation. (RHD procedures that do not affect the radiation protection program, e.g. financial or personnel administration, are not considered to be radiation procedures and are not covered in this procedure.)

Radiation record - information on a specific category, e.g. radiation sources, radioactive materials, radiation exposures, etc., and related to a single key datum, e.g. one person, inventory item, waste package, etc.

RHD - Radiological Health Department.

RSC - Radiation Safety Committee.

RSO - Radiation Safety Officer.

RPR - acronym referring to all radiation procedures and records.

AUTHORIZATION AND ADOPTION OF RPRs

The RSO may make ministerial changes to any RPR that do not affect policy statements. Changes to policy

statements shall be submitted to the RSC for approval; any proposed change that affects license conditions or commitments previously made to the licensing agency shall be submitted to the licensing agency as a request for license amendment. Revisions to RPRs that affect only the functions and efforts of RHD personnel may be implemented immediately, but shall be submitted to the RSC for information and documentation. Revisions that potentially affect the requirements placed on radiations users shall be reviewed and approved by the RSC before they are implemented, unless the change is mandated by the licensing agency.

The RSO shall maintain a master chronological file of all revisions to RPRs and the minutes of the RSC shall include the revisions reviewed at any meeting.

FORMAT FOR PROCEDURES

Radiation procedures should contain the following elements, if appropriate:

Title - short and concise, but informative.

Header or footer - appearing on every page and containing the procedure number, and abbreviated title, and the date issued or revised. The date shall correspond to the date of the RSC meeting in which the RPR was reviewed and approved.

Purpose - a short statement of the objective and applicability of the procedure.

Policy - consisting of a statement of University, RSC or RHD policy that necessitates the procedure. In general, the policy statement in the RPR is incorporated into the *Radiation Safety Policy Manual*.

Definitions - limited to unique terms required to understand the procedure.

Instructions - detailed procedures under as many sub-headings as are appropriate.

References - a listing of regulations, regulatory guidance documents and publications of advisory organizations that are directly related to the procedure; any deviations or exceptions from the guidance contained in the references should be explicitly explained in the procedure.

Forms or other record formats - a sample or facsimile of each form or record used for management of any data generated by operations covered by the procedure should be appended to the procedure.

DESIGN CRITERIA FOR RECORDS

The radiation protection records system shall be designed and maintained according to the following essential criteria:

1 All records for which there is a retention requirement shall be on paper ("hard" copies). Data may be entered initially into the database, but file copies shall be printed out for permanent retention. Note that a variety of listings, reports and summaries may be generated and used in routine operations, but they are not classified as "records" unless they have a specified retention requirement. Permanent records are those that have no defined limit to the required retention time; individual exposure records are considered to be permanent. Temporary records have prescribed retention times, typically varying from 3 to 10 years.

2 Filing systems for all records shall be designed with future recoverability as a primary consideration; this is of paramount importance for permanent records, for which **recovery shall not be dependent upon the memory of any particular individuals**. The identification of each file, and the key to each record, shall be the data most likely to be available and used to initiate the search for the information. For example, general information on radiation protection policies and practices are most likely to be desired for a specific time period, so general programmatic documentation is filed chronologically by years. On the other hand, records of individual assignments or authorizations, radiation safety training, radiation monitoring, exposures, incidents, etc. are most likely to be sought in connection with a particular individual and shall, therefore, be filed alphabetically by surname.

3 Procedures and forms used to produce records shall assure completeness and specificity of the information, and shall include the date and positive identification of the person who created or revised it. Procedures shall also assure the confidentiality of personal and proprietary information.

DESIGN CRITERIA FOR FORMS

Many records consist of preprinted forms containing information entered by RHD personnel or by radiation users. Forms should be designed according to the criteria listed below and shall be approved by the Director or RSO before use.

1 A form should be given a brief title that clearly identifies its purpose and that can be remembered easily by individuals who use it rarely and may not remember a number. A form number is usually assigned also, primarily for abbreviated referencing by those who use it frequently. Form numbers are generally extensions of the number of the procedure that contains the instructions for its use.

2 Forms should carry an appropriate header or footer identifying the form number, title, and the date of issue or revision. Multiple-page forms should have spaces for page numbers, initials and dates on each page.

3 Forms should contain specific spaces for entering data; each space should be unambiguously labeled as to the type and units of the datum to be entered. Generally accepted terminology, abbreviations and units should be used; **unorthodox notations are not to be used**. Every form should provide space for signature(s) or initials and date(s) prepared for every individual completing any portion of the form. The required distribution and filing of the record should be stated on each form.

4 Forms should be provided with margins of at least 3/4 inch on all sides to minimize loss of information due to copy misalignment, punching holes, mounting in notebooks or file folders, as well as to enhance appearance.

UNFORMATTED RECORDS

For data that are to be collected and recorded by means other than preprinted forms, specific check lists should be prepared and incorporated into written procedures to assure that the records are consistent and complete. Unformatted written records shall include precise identification of the nature of the record and the originator's signature and date prepared.

RECORD FILES AND STORAGE

The major files of radiation records maintained by the RSO and the RHD are:

Radiation Safety Committee Minutes

The RSC minutes contain a record of all official actions of the Committee, e.g adoption of policy statements and authorizations of specific radiation users. Major activities of the RSO and the entire radiation protection program are reported regularly to the RSC even when specific action by the committee is not required. As a result, the minutes of RSC meetings serve as the primary mechanism for documentation of the overall radiation program. One complete copy of the RSC minutes is sent to the University Archivist each year. Another complete copy is maintained in the RHD office.

Radiation Users

Records of all individuals identified as radiation users are maintained indefinitely. These records are filed alphabetically by names, but a unique number is used as the key to the personnel database file. The records for individual radiation users contain data on radiation safety training and experience, as well as on personal radiation monitoring and exposures.

Responsible (Authorized) Users

Records of authorizations of responsible users and general information pertaining to the personnel or activities of the entire group for whom the authorized user is responsible, are filed alphabetically by the responsible users names. In the computer database, a "responsible user number" is assigned sequentially and serves as the key to the file.

Radiation Users

Personal data on individual radiation users are maintained in file folders alphabetized by surnames. These records are treated as confidential and shall be accessible only to those with an official need to know. Personal records shall not be released to other individuals or organizations without the written permission of the individual. In the computer database, personal records are also identified by a sequential number as the key.

Exposure and ALARA Summaries

Summaries of radiation exposure monitoring and doses received shall be prepared for and provided to each radiation user annually. A summary of occupational doses and of the investigations conducted to implement the ALARA program shall be provided to the Radiation Safety Committee and the Reactor Safety Committee quarterly.

Both individual personal data records and responsible user records are combined in the permanent files of inactive users.

Area Surveys

Surveys of radioisotope laboratories, and other areas where radiation sources are used, are filed alphabetically by name of responsible user. However, this file is separate from the main authorization file, since the required retention times are different.

Radiation Devices

Records of special equipment used for producing, using or controlling radiation are placed in a "devices" file. Examples of the records in this file are accelerators, x-ray machines, self-contained irradiators, calibration sources, etc.

Radioactive Materials

Licenses authorizing the possession of radioactive materials are filed by license numbers in a license file. Licensing information on other institutions to which radioactive materials may be sent is maintained in a file alphabetized by institution names.

The current inventory of radioactive materials possessed by the University is maintained in the RHD computer database in a form that allows selective outputs of inventory by users, by buildings, by form of the material, by individual nuclides, etc. Records of receipts, transfers and dispositions of radioactive materials, including surveys of incoming packages and transfers to waste containers, are retained in a chronological file. A summary of the University's total possession by form and nuclide that permits comparison with license limits is printed out periodically to be retained with the RSC minutes.

Records of shipments of radioactive wastes to waste brokers or to disposal sites are kept in a separate waste shipments file.

Environmental Releases and Monitoring

Records of environmental releases and monitoring are maintained in chronological files. A summary is included with the minutes of the RSC annually, with sufficient information for linkage to the primary files.

INDEXING

Each folder or file cabinet containing radiation records shall be provided with an index and a means of keeping it current. Indexing takes several different forms; the file of inactive radiation users occupies several file cabinets, and the index consists only of alphabetical labeling on the file drawers. The records of active radiation users are also filed alphabetically, but occupy only one file cabinet. However, active users are also entered in the RHD database, which provides additional means of indexing, e.g. by social security number, by dosimetry devices, by department or location, etc.

In some cases, all of the records on a subject may be contained in one, or just a few, file folders. File folders should be provided with an index to their contents to expedite recovery of specific information.

A current index to all RPRs is prepared and distributed whenever procedures are added or revised. The index to RPRs includes the RPR number, title and date of latest revision.

DISTRIBUTION OF RPRs

All RPRs are distributed to members of the RSC and to all RHD personnel.

Personal data forms are provided to radiation users when they first attend a radiation safety training course or first begin work with radiation sources, whichever occurs first. Responsible user application forms are provided upon request.

Most radiation users need only a few RPRs pertaining specifically to their authorized uses. RPRs are distributed only to the responsible users to whom they apply. Anyone else may obtain a copy of these procedures by specific request. As part of their routine audits of radiation users'

facilities, Radiation Analysts shall ascertain that the users have the most recent versions of the appropriate RPRs.

DATABASE ENTRIES AND REVISIONS

Many items in the computerized database are inter-related, and changes to one record may have unexpected results in another record. Database records are to be entered or edited only by individuals who have been specifically trained and authorized by the Director or Database Manager to manipulate the specific file or records.

Changes to data on responsible users or individual radiation users shall be verified on the printed summary sheet as soon as possible after a new or revised entry is made. The summary sheet shall then be filed in the individual's file folder.

The Database Manager shall ensure that backups of all electronic files are maintained to insure against loss.

RECORD RETENTION

Records are listed below in categories according to their required retention time. The Director of the RHD is responsible for assuring that records are retained and sent to University archives, as appropriate.

Records to be retained **Indefinitely**

1 All licenses and registrations, including applications, supporting information, responses to agency queries, amendments, etc.

2 All program documentation, including minutes of RSC meetings and all RPRs.

3 All records of individual radiation users' training and exposure monitoring data, including the determination of need for personal dosimeters or routine bioassays, dosimeter assignments, dosimetry and bioassay results, investigations of unusual exposure incidents, etc.

4 All measurements and evaluations obtained for the purpose of determining individual exposures, e.g. area surveys, air samples, etc.

5 Records of receipts, transfers and disposals of radioactive materials.

6 All measurements and evaluations of effluents and environmental radioactivity, including summaries of quantities released to the atmosphere or to the sanitary sewer, measurements of concentrations in effluents or environmental media, etc.

Records to be retained at least **10 years**

7 Records of misadministrations, containing names of all individuals involved in the event (physician, allied health personnel, patient, referring physician), patient's social security or identification number, brief description of the event, effect on the patient, and action taken to prevent recurrence (UDRC R313-32-33).

Records to be retained at least **5 years**

8 Records of leak test of sealed sources.

Records to be retained at least **3 years** or until inspected by the licensing agency

9 Records of surveys of incoming packages of radioactive materials, surveys of laboratories for contamination and records of instrument calibrations, unless directly used to determine exposures to personnel, in which case they shall be retained indefinitely.

10 Reports of audits and other reviews of program content and implementation.

REFERENCES

National Council on Radiation Protection and Measurements, *Maintaining Radiation Protection Records,* NCRP Report No. 114, Bethesda, MD, 1992.

University of Utah:

Policy and Procedures Manual

Radiation Safety Policy Manual

Utah Division of Radiation Control, *Utah Radiation Control Rules*:

Standards for Protection Against Radiation, R313-15.

Notices, Instructions and Reports to Workers by Licensees or Registrants - Inspections, R313-18.

Medical Use of Radioactive Material, R313-32.