Document Preparation Profile (DPP)

1. IDENTIFICATION

Document Category:	**Safety Guide**
Working ID:	**DS434**
Proposed Title:	**Radiation Safety of Radioisotope Production Facilities**
Proposed Action:	**new document**
Published Title/Date:	**N/A**
Safety Series No.:	**N/A**
SS Committee(s):	**RASSC/NUSSC/WASSC/TRANSSC**
Technical Officer(s):	**E.H. Reber**

2. BACKGROUND

Radioisotopes are used worldwide in a range of medical, industrial, research and academic applications. Most of these radioisotopes are produced in reactors and particle accelerators. The production of radioisotopes often involves the handling of large quantities of radioactive material and the operation of reactors and particle accelerators that can present significant radiation hazards to workers, members of the public, and the environment.

In 2003 there were 278 research reactors in operation, of which approximately 70 were deemed useful for regular radioisotope production. [IAEA TECDOC-1340] In 2006 it was estimated that there were approximately 350 cyclotrons in operation worldwide that were used to some extent for radioisotope production. [IAEA-DCRP/2006] The number of institutions that operate cyclotrons and manufacture and distribute radiopharmaceuticals that are used in positron emission tomography and single photon emission computed tomography is significant and growing. Another significant emerging trend is the use by medical institutions of user-friendly compact medical cyclotrons.

3. OBJECTIVE AND JUSTIFICATION

The IAEA has produced several publications on radioisotope production techniques and the establishment of associated facilities. Portions of these documents address radiation safety issues. However, no IAEA document, a safety standard or otherwise, has been produced that provides comprehensive recommendations on the application of the requirements of the BSS and other requirements of the safety standards to the production of radioisotopes. Therefore, in consideration of the current situation and anticipated future trends in radioisotope production, as well as the absence of a relevant facility-specific guidance document for use by regulatory bodies, the subject document has been proposed. The need for a new safety guide on this topic is evidenced by its inclusion in the Reference Set of Safety Guides for the Long Term.

4. POSITION IN THE OVERALL STRUCTURE OF THE RELEVANT SERIES AND INTERFACES WITH EXISTING AND/OR PLANNED PUBLICATIONS

The proposed safety guide will provide recommendations of measures that should be taken to ensure fulfilment of the safety requirements included in the following documents:

- BSS, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources,
- GS-R-2, Preparedness and Response for a Nuclear or Radiological Emergency
- GS-R-3, The Management System for Facilities and Activities
- GSR Part 5, Predisposal Management of Radioactive Waste
- TS-R-1, Regulations for the Safe Transport of Radioactive Material

The proposed safety guide will be part of a group of facility- and activity-specific radiation related guides that includes:

- DS399, Safety in Medical Uses of Ionizing Radiation
- DS408, Radiation Safety in Industrial Radiography
- DS409, Radiation Safety of Gamma, Electron and X ray Irradiation Facilities
- DS410, National Strategy for Regaining Control over Orphan Sources and Improving Control over Vulnerable Radioactive Sources
- DS411, Orphan Radioactive Sources and Other Radioactive Material in the Metal Recycling and Production Industries
- DS419, Radiation Safety of Well Logging Sources
- DS420, Radiation Safety of Nuclear Gauges
- RS-G-1.6, Occupational Radiation Protection in the Mining and Processing of Raw Materials

The proposed safety guide will take account of the guidance provided in, and will include references to, the following safety guides:

- RS-G-1.1, Occupation Radiation Safety
- RS-G-1.2, Assessment of Occupational Exposure due to Intakes of Radionuclides
- RS-G-1.3, Assessment of Occupational Exposure due to External Sources of Radiation
- RS-G-1.8, Strategies for Environmental and Source Monitoring for Public Protection Purposes
- RS-G-1.10, Safety of Radiation Generators and Sealed Radioactive Sources
- RS-G-1.4, Building Competence in Radiation Protection and the Safe Use of Radiation Sources
- RS-G-1.7, Application of the Concepts of Exclusion Exemption and Clearance
- RS-G-1.9, Categorization of Radioactive Sources
- DS401, Justification of Practices
- WS-G-2.3, Regulatory Control of Radioactive Discharges to the Environment
- WS-G-2.5, Predisposal Management of Low and Intermediate Level Radioactive Waste
- WS-G-2.7, Management of Waste from the Use of Radioactive Materials in Medicine, Industry, Agriculture, Research and Education
- WS-G-6.1, Storage of Radioactive Waste

- GS-G-3.1, Application of the Management System for Facilities and Activities
- Safety Standards Safety Series No. 1, Safe Handling of Radionuclides

The Division of Physical and Chemical Sciences (NAPC) of the Department of Nuclear Sciences and Applications has developed several documents dealing with the production of radioisotopes and the development of the proposed safety guide will be coordinated with this division. The following documents that have been developed by NAPC will be considered in the development of this safety guide:

- IAEA-TECDOC-1340, Manual for Reactor Produced Radioisotopes (2003).
- IAEA-TECDOC-1430, Radioisotope handling facilities and automation of radioisotope production (2004).
- IAEA-TECDOC-1065, Production Technologies for Molybdenum-99 and Technetium-99m (1999).
- TRS 465, Cyclotron Produced Radionuclides: Physical Characteristics and Production Methods (2008).
- TRS 468, Cyclotron Produced Radionuclides: Principles and Practice (2009).
- TRS 471, Cyclotron Produced Radionuclides: Guidelines for Facility Development (2009).

The various sections of the safety guide that address the specialties of various organizational units within NS will be coordinated with those units.

5. OVERVIEW

SCOPE

The recommendations of this document will address the radiation safety and protection aspects of the process whereby radioisotopes that have been produced in reactors or accelerators (principally cyclotrons), or purified from other sources are then processed into radioactive products. The recommendations will also address elements of the design and operation of accelerators (principally cyclotrons) that pertain directly to the production of radioisotopes.

The following types and portions of facilities are within the scope of the proposed safety guide:

- Facilities that process targets that have been irradiated in reactor facilities or subjected to the charged particle beam of an accelerator to produce radioisotopes.
- Radioactive material processing and radiation source fabrication facilities.
- Accelerator facilities with energies of less than 70 MeV/nucleon that are operated principally to produce radioisotopes. This document addresses these four categories of accelerators:
    - Low energy (<20 MeV) cyclotrons for medical radioisotope production.
    - 20 - 40 MeV isotope production cyclotrons
    - > 40 MeV cyclotrons for mixed research and radioisotope production.
    - Linear accelerators used for radioisotope production

The design and operation of reactors is outside the scope of this document. Also, the use of radioactive material following its manufacture, and standards and quality assurance procedures that pertain to its production are outside the scope of this document. The production of fissile material is outside the scope of this document.

Centralized radiopharmacies that formulate radiopharmaceuticals from bulk quantities of isotopes or generators are outside the scope of this document.

Radiation generators (e.g., linear accelerators used in radiotherapy applications) that produce radioisotopes as a byproduct of their operation are outside the scope of this document.

The principal issues covered in the safety guide will be:

— the types of facilities and activities within the scope of the document;

— the principal elements of practices;

— individual monitoring of workers;

— workplace monitoring;

— effluent and environmental monitoring;

— personal protective equipment;

— control of radioactive sources;

— site selection;

— facility and equipment design;

— testing and maintenance of equipment;

— radioactive waste management;

— transport of radioactive material;

— emergency planning and preparedness;

Please see the attached proposed table of contents for further details.

6. PRODUCTION: Provisional schedule for preparation of the document, outlining expected dates for:

Approval of DPP by the Coordination Committee: August 2009
Approval of DPP by the Safety Standards Committees: November 2009
Approval of DPP by the CSS: March 2010
Approval of draft by the Coordination Committee: 2011
Approval by the Safety Standards Committees for submission to Member States for comments: 2011
Approval of the revised draft by the Coordination Committee: May 2012
Review in NS-SSCS: 2012

Approval by the Safety Standards Committees for submission to the CSS;
Endorsement by the CSS: 2012
Submission to Publications Committee: 2012
Approval by the Board of Governors, as appropriate
Target publication: 2012

7. RESOURCES

Estimated resources involved by the Secretariat and the Member States

CONTENTS

Maintenance and calibration
Use of radiation survey meters
Types of surveys
Records of radiation surveys

7. EFFLUENT AND ENVIRONMENTAL MONITORING
Air effluent monitoring
Liquid effluent monitoring
Environmental monitoring

8. PERSONAL PROTECTIVE EQUIPMENT

9. CONTROL OF RADIOACTIVE SOURCES
Confirmation that recipients of sources are authorized to receive them
Access Control to radioactive material
Nuclear material

10. SITE SELECTION

11. FACILITY (AND EQUIPMENT) DESIGN
Cyclotron and accelerator design (brief background comments)
Interlocks
Internal work flow
Overall work flow
Materials and equipment flow
Radioactive material transfer devices; rabbit transfer
Considerations for future decommissioning
Work surfaces and floors
Hot Cells
Shielding
Air flow
Fabricated from materials that can be decontaminated
Remote-handling tongs, master/slave manipulators
Inner surfaces
Fume hoods
Air flow
Fabricated from materials that can be decontaminated
Analytic laboratory
Sterile environment considerations
Target design
Shielding
Interlocked systems on accelerators, high activity hot cells, transfer systems
Ventilation
Air flow
From least contaminated to the most
Effluent exhaust, filtration
Warning signs and symbols and labelling
Posting of information
Fire protection
Electrical System (Power failure)
Considerations with regard to external events
Remote/automatic operation of cyclotron facilities
Radioactive waste storage area
Facility support infrastructure modifications

12. TESTING AND MAINTENANCE OF EQUIPMENT
    - Periodic tests
    - Ventilation
    - Radiation monitoring equipment
    - Interlocks
    - Dose calibrators
    - Records
    - Facility maintenance and modification
13. RADIOCTIVE WASTE MANAGEMENT
    - Waste handling procedures
    - Decay in storage
    - Waste minimization
    - Preparation of waste shipments
14. TRANSPORT OF RADIOACTIVE MATERIAL
    - Transport requirements
    - Preparation of packages for shipment
    - Survey of transport packages
15. EMERGENCY PLANNING AND PREPAREDNESS
    - Development of emergency plans
    - Emergency equipment
    - Training
    - Periodic reviews of emergency plans

ANNEX

Example Facility Diagrams:

- Low energy (<20 MeV) cyclotrons for medical radioisotope production.
    - Bunker type
    - Self-shielded
- 20 – 40 MeV isotope production cyclotrons
- > 40 MeV cyclotrons for mixed research and radioisotope production.
- Generic facility for processing various radionuclides and quantities