Grading of the Management System Requirements to the Safe Transport of Radioactive Materials

Y.E. Tawfik
ETRR-2 Complex, Egyptian Atomic Energy Authority, Cairo – Egypt

Received: 1/3/2016  
Accepted: 7/6/2016

ABSTRACT

A graded approach is applicable in all stages of the lifetime of a research reactor. During the lifetime of a research reactor, any grading that is performed should be such that safety functions and operational limits and conditions are preserved, so that there are no undue radiological hazards to workers, public or environment. The grading of activities should be based on safety analyses, and regulatory requirements. Other elements to be considered in grading are the complexity and the maturity of the technology, operating experience associated with the activities and the stage in the lifetime of the facility. In this application, a graded approach is applied for the management system requirements to the safe transport of radioactive material in ETRR-2 research reactor facilities. The Radioisotopes produced at the ETRR-2 facilities could be transported using one of the following packages; Cardboard box, Type A container, Type B(U) and B(M) containers. This application, in such facilities, is involved in the design and manufacture of transport packages typically use a component based graded approach and qualitative expressions of risk based on the safety consequences of failure of the packaging component. The main steps to apply the grading approach in this application are; identify the package type according to applicable transport regulations: classify the package by developing a list of the packaging components and the code used in the design, fabrication, use, inspection or testing and assign a quality grade to each items (systems, structures, or components); and specify the management controls required and assign a quality grade to each items.

Keywords: Grading Approach / Management System / Research Reactors / Transport of Radioactive Materials

INTRODUCTION

A graded approach is the process of ensuring that the level of analysis, documentation, and actions required by the regulatory framework are conforming to the safety of a research reactor (RR) facility are commensurate with:

(1) The relative importance to safety, safeguards, and security;
(2) The magnitude of any hazard involved;
(3) The life cycle stage of a facility;
(4) The particular characteristics of a facility; and
(5) Any other relevant factors.[1]

The graded approach is defined as follows according to IAEA Safety Glossary.[2]

1. For a system of control, such as a regulatory system or a safety system, a process or method in which the stringency of the control measures and conditions to be applied is commensurate, to the extent practicable, with the likelihood and possible consequences of, and the level of risk associated with, a loss of control. An example of a graded approach in general would be a structured method by means of which the stringency of application of requirements is varied in accordance with the circumstances, the regulatory systems used, the management systems used, etc. For example, a method in which:
(1) The significance and complexity of a product or service, activity or controls are determined;

(2) The potential impacts of the product or service on health, safety, security, the environment, economical aspects and the achieving of quality and the organization’s objectives are determined;

(3) The consequences if a product fails or if a service is carried out incorrectly are taken into account.

2. An application of safety requirements that is commensurate with the characteristics of the practice or source and with the magnitude and likelihood of the exposures. In practical terms, a graded approach applies to management system requirements of a product, item, system, structure or component, service, activity or controls of a process commensurate with its relative importance, complexity, variability, maturity, potential impact on safety, health, environmental, security, quality and economical aspects. By the application of a graded approach, the controls, measures, training, qualification, inspections, detail of procedures, etc. might be adapted to the level of risk or importance for safety, health, environmental, security, quality and economical aspects. In evaluating these aspects the system is to be considered holistically. The graded approach will result in an effective application of appropriate resources (time, money, staff, etc.) with regard to defined requirements. For each specific product, item, system, structure or component, service, activity or controls the graded approach will affect the type and level (extent and depth) of controls applied, for example:
   - The type and level of planning and analysis;
   - The type and level of verification, inspection and testing;
   - The review and approval requirements of activities, documents and records;
   - The type and level of qualification and training for individuals; and
   - The type and level of controls can change from organization to organization, with time and with the state or the life cycle stage of the facility or activity [3,4].

Objective of the Graded Approach

- The objective of the graded approach is to adjust application of the safety requirements for analysis, evaluation and documentation to the potential hazards associated with the reactor facilities.

- The desired effect of applying the graded approach is that resources will be used more efficiently and produce maximum benefit.

- The graded approach should be used to eliminate unproductive or unnecessary features or activities.

Application of a graded approach may include:

- Determining the significance and complexity of a product or service, the maturity of the technology involved and the experience with its application;

- Evaluation of the impacts of a product or service on health, safety, security, the environment, quality and achieving the organization’s objective; and

- Assessing the consequences of failure of a product or incorrect performance of a service.\(^{[2,3]}\)
GRADED APPROACH APPLICATIONS IN ETRR-2 REACTOR

The ETRR-2 complex consists of the ETRR-2 Multipurpose Reactor, the Fuel Manufacturing pilot plant (FMPP), and the Radioisotope Production plant (RPF). The ETRR-2 is a 22 MW multipurpose reactor, while the FMPP plant produces the fuel elements for the reactor, and the RPF facility makes use of the irradiation capabilities with which the ETRR2 reactor was designed to produce radioisotopes for medicinal and industrial uses. These three facilities are located in the Inshas site – EAEA – Egypt. The RPF was designed for the production of Mo-99, I-131, I-125, Cr-51, Co-60 and Ir-192 radioisotopes, and has also installations for the loading of Tc-99m generators as from the Mo-99. The Mo-99 produced is used to load Tc-99m generators and meet Egypt's local demand, and also for exportation. Both Mo-99 and Tc-99m as well as I-131, I-125 and Cr-51 are used in nuclear medicine. In the case of Ir-192, wires are produced for nuclear medicine and sealed sources for industrial gammagraphy \[5\]. The following is a typical application of graded approach on the management system requirements to the safe transport of radioactive material \[6\].

Types of Transport of Radioactive Material Package at ETRR-2 Facilities

The Radioisotopes produced at the RPF-ETRR-2 could be transported by using one of the following packages:

(a) Cardboard box
(b) Type A container
(c) Type B(U) and B(M) containers

The size and content of each package is as follows:

(a) Cardboard box

Size 1: 11x11x12 cm
Size 2: 24x24x24 cm
Size 3: 34x34x34 cm

Its contents:
- Vial (Glass or stainless steel)
- Shielding (Lead shielding)
  - Wall thickness 1: 0.5 cm
  - Wall thickness 2: 2 cm
  - Wall thickness 3: 3 cm
- Inner packaging foam (Spacer/ shock absorber)
- Steel can (Package)
- Overpack (Spacer and cardboard box)
- Steel can: Dia. 87mm x H 116mm

(b) Type A container

- Vial (Glass or plastic or stainless steel)
- Type A container (Shielding/ Package)
- Overpack (Spacer and steel can)

(c) Type B(U) and B(M) container

- Vial (Glass or plastic or stainless steel)
- Stainless steel container
- Type B(U) or B(M) container (Shielding/ Package)
- Outer packaging (Spacer and wood box) \[7\]
Activity Limits and Classification


Radioactive material is assigned to one of the UN numbers specified in Table 1. Table (1): Shipping name and description of main ETRR-2 products and packages[8].

<table>
<thead>
<tr>
<th>Assignment of UN numbers</th>
<th>Shipping name and description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Excepted package</strong></td>
<td></td>
</tr>
<tr>
<td>UN 2908</td>
<td>Radioactive material, excepted package-empty packaging</td>
</tr>
<tr>
<td>UN 2909</td>
<td>Radioactive material, excepted package-articles manufactured from depleted uranium or tungsten alloy.</td>
</tr>
<tr>
<td>UN 2910</td>
<td>Radioactive material, excepted package-limited quantity of material</td>
</tr>
<tr>
<td><strong>Type A package</strong></td>
<td></td>
</tr>
<tr>
<td>UN 2915</td>
<td>Radioactive material, Type A package, non-fissile or fissile-excepted</td>
</tr>
<tr>
<td><strong>Type B(U) package</strong></td>
<td></td>
</tr>
<tr>
<td>UN 2916</td>
<td>Radioactive material, Type B(U) package, non-fissile or fissile-excepted</td>
</tr>
<tr>
<td><strong>Type B(M) package</strong></td>
<td></td>
</tr>
<tr>
<td>UN 2917</td>
<td>Radioactive material, Type B(M) package, non-fissile or fissile-excepted</td>
</tr>
</tbody>
</table>

2. Basic Radionuclide Values

The following basic values for individual radionuclides are given in Table 2:

(a) $A_1^*$ and $A_2^{**}$ in TBq;
(b) Activity concentration limits for exempt material in Bq/g;
(c) Activity limits for exempt consignments in Bq.
Table (2): Basic Radionuclide Values \[^8\]

<table>
<thead>
<tr>
<th>Radionuclide (Atomic number)</th>
<th>A1 (TBq)</th>
<th>A2 (TBq)</th>
<th>Activity concentration for exempt material (Bq/g)</th>
<th>Activity limit for an exempt consignment (Bq/g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cr-51</td>
<td>3 x 10^3</td>
<td>3 x 10^3</td>
<td>1 x 10^3</td>
<td>1 x 10^7</td>
</tr>
<tr>
<td>I-125</td>
<td>2 x 10^3</td>
<td>3 x 10^3</td>
<td>1 x 10^3</td>
<td>1 x 10^6</td>
</tr>
<tr>
<td>I-131</td>
<td>3 x 10^0</td>
<td>7 x 10^4</td>
<td>1 x 10^2</td>
<td>1 x 10^6</td>
</tr>
<tr>
<td>Ir-192</td>
<td>1 x 10^0</td>
<td>6 x 10^4</td>
<td>1 x 10^1</td>
<td>1 x 10^4</td>
</tr>
<tr>
<td>Mo-99</td>
<td>1 x 10^0</td>
<td>6 x 10^4</td>
<td>1 x 10^2</td>
<td>1 x 10^6</td>
</tr>
<tr>
<td>Tc-99m</td>
<td>1 x 10^1</td>
<td>4 x 10^6</td>
<td>1 x 10^2</td>
<td>1 x 10^7</td>
</tr>
<tr>
<td>Co-60</td>
<td>4 x 10^{-1}</td>
<td>4 x 10^{-1}</td>
<td>1 x 10^1</td>
<td>4 x 10^5</td>
</tr>
</tbody>
</table>

(*) A1 is the activity value of a special form radioactive material listed in Table 2 and is used to determine the activity limits for the requirements of the safe transport of radioactive material regulations.

(**) A2 is the activity value of a radioactive material, other than special form radioactive material in Table 2 and is used to determine the activity limits for the requirements of the safe transport of radioactive material regulations.

3. Classification of Packages

3.1 Classification as Excepted Package

A package classified as an excepted package by the following conditions:

(a) It is an empty package having contained radioactive material;

(b) It contains instruments or articles not exceeding the activity limits specified in Table 3;

(c) It contains articles manufactured of depleted uranium or Tungsten alloy;

(d) It contains radioactive material not exceeding the activity limits specified in Table 3.\[^8,9\]

Table (3): Activity limits excepted packages \[^8\]

<table>
<thead>
<tr>
<th>Physical state of contents</th>
<th>Instrument or article</th>
<th>Materials</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Item limits</td>
<td>Package limits</td>
</tr>
<tr>
<td>Solids :</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Special form</td>
<td>10^{-2} A1</td>
<td>A1</td>
</tr>
<tr>
<td>Other forms</td>
<td>10^{-2} A2</td>
<td>A2</td>
</tr>
<tr>
<td>Liquids :</td>
<td>10^{-3} A2</td>
<td>10^{-1} A2</td>
</tr>
</tbody>
</table>
3.2 Classification as Type A Package

Type A packages not contain activities greater than either of the following:

(a) For special form radioactive material — $A1$;
(b) For all other radioactive material — $A2$.

3.3 Classification as Type B(U), Type B(M)

Type B(U) and Type B(M) packages classified in accordance with the authority certificate of approval for the package issued by the country of origin of design.

Type B(U) and Type B(M) packages, if transported by air, are not contain activities greater than the following:

(a) For low dispersible radioactive material — as authorized for the package design as specified in the certificate of approval;
(b) For special form radioactive material — $3000A1$ or $105A2$, whichever is the lower;
(c) For all other radioactive material — $3000A2$.[10]

Annex (1) summarizes the classification of all type of the packages.

Grading steps of the Management System Requirements to the Safe Transport of Radioactive Materials

Steps in the grading approach are:

1) Identify the package type according to applicable transport regulations;
2) classify the package by developing a list of the packaging components and the code used in the design, fabrication, use, inspection or testing and assign a quality grade to each items (as illustrated in Table 4);
3) Specify the management controls required and assign a quality grade to each items (as illustrated in Table 5).

Many quality requirements are specified by applicable codes or standards for design, fabrication, inspection and testing that are determined as a result of grading during the initial stages of the package fabrication. Quality codes and standards can vary between different components of a single package type and between similar components of packages of different types. The package materials can include bulk material such as metal plate, sheet, castings, weld metal and forgings. Items fabricated by sub-tier suppliers (e.g. seals, bolts, pressure relief valves, rupture discs and closure assemblies) can also be included. Typically, traceability of material, control of chemical and physical properties of materials and segregation of non-conforming materials are used to ensure proper fabrication. Fabrication requirements can vary between different components of a single type of container and between similar components of containers of different categories, according to the materials used in the construction. For example, welds that join components should be assigned the same quality grade as the higher level component unless a lower grade can be justified. Welds that join a component (e.g. a longitudinal seam weld for a cylinder) should be assigned the same quality grade as the component of which they are part. Many requirements for fabrication processes (e.g. cutting, welding and heat treatment) are specified in applicable codes. However, for some “special” processes (e.g. the pouring of gamma shielding material) no specific code exists and approved procedures are needed to control the task. Where manufacturers do not have an approved management system for Grade 1 component materials such as foam, honeycomb or wood (used in impact limiters), concrete or lead (used in shielding) and polymers (used in seals), the suppliers of packaging can use the manufacturer’s management responsibility on designers to specify the properties and characteristics of materials, and on the manufacturers to comply with these specifications.
Table (4): Quality grades based on the sequences of failure

<table>
<thead>
<tr>
<th>Quality grade</th>
<th>Safety classification</th>
<th>Consequences failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1</td>
<td>Safety class- critical to safe operation</td>
<td>Grade 1 items are those directly affecting package leak tightness or shielding, or, for packages of fissile material, those directly affecting geometry and thus control of criticality. Examples include the primary and secondary containment vessels, outer and inner O-rings on the vessels and lead shield.</td>
</tr>
<tr>
<td>Grade 2</td>
<td>Safety significant- major impact on safety</td>
<td>Grade 2 items are systems, structures or components whose failure could indirectly affect safety in combination with a secondary event or failure. Examples include impact absorbers that provide impact protection between the primary and secondary containment systems during an accident.</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Production support- minor impact on safety</td>
<td>Grade 3 items are those systems, structures or components whose malfunction would not affect the effectiveness of the packaging and so would be unlikely to affect safety. Examples include devices that provide evidence of tampering, such as secure locks and seals and package identification plates.</td>
</tr>
<tr>
<td>Grade 4</td>
<td>Production support- not impact on safety</td>
<td>Grade 4 items are those systems, structures or components whose malfunction would not affect on the safety or quality of the packaging. Examples include such a non-graded item is software that facilitates routine operation, handling or use of the package or packaging.</td>
</tr>
</tbody>
</table>

Table (5): Graded management controls

<table>
<thead>
<tr>
<th>Graded management controls</th>
<th>Quality grades</th>
</tr>
</thead>
<tbody>
<tr>
<td>The suppliers have a management system based on applicable criteria established in an acceptable national or international standard.</td>
<td>X</td>
</tr>
<tr>
<td>The manufacturing planning specifies complete traceability of raw materials and the used of certified welders and processes.</td>
<td>X</td>
</tr>
<tr>
<td>The procurement documentation for materials for services specifies that only suppliers from qualified vendor lists are used.</td>
<td>X X</td>
</tr>
<tr>
<td>Verification planning (inspection and testing) requires the use of qualified inspectors (i.e. individuals performing non-destructive examinations such as radiography and ultrasonic testing are qualified in accordance with recommended practices described in appropriate national or international standards).</td>
<td>X X</td>
</tr>
<tr>
<td>Only qualified auditors and lead auditors perform audits</td>
<td>X X</td>
</tr>
<tr>
<td>Fabrication and assembly records, results reviews, inspections, tests and audits, results of the monitoring of work performance and materials analyses, and results of maintenance, modifications and repair activities are maintained.</td>
<td>X X</td>
</tr>
<tr>
<td>The procurement of materials need not be from a qualified vendor list.</td>
<td>X X</td>
</tr>
<tr>
<td>Items are purchased from a catalogue of “off the shelf” items.</td>
<td>X</td>
</tr>
<tr>
<td>When the item is received, the material is identified and checked for damage.</td>
<td>X</td>
</tr>
<tr>
<td>Self-assessments rather than independent assessment are the primary method of assessing and verifying performance.</td>
<td>X</td>
</tr>
<tr>
<td>Records are maintained in temporary files for a specific retention period (e.g. six months) after shipment.</td>
<td>X</td>
</tr>
</tbody>
</table>
Quality grades applied to transport packages

The level of management control applied to a package is required to be commensurate with the hazard posed by the radioactive contents. The following guidance is applicable to each category of package listed. However, it gives a general indication of the degree to which the management system requirements are to be applied.

Table (6): Quality grades applied to transport packages

<table>
<thead>
<tr>
<th>Activity</th>
<th>Quality grades</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>packaged Type A(non-fissile and fissile)</strong></td>
<td>Grade 1 Grade 2 Grade 3</td>
</tr>
<tr>
<td>Instrumentation and processes used in the determination of the radioactive contents and package radiation levels. All other aspects, such as design, manufacture, etc.</td>
<td>X</td>
</tr>
<tr>
<td><strong>Fissile packages (other than Type B packages)</strong></td>
<td>X</td>
</tr>
<tr>
<td>Criticality assessment and other factors affecting the assumptions in criticality assessment. Other aspects except where there is minimal effect on safety. Other aspects where there is minimal effect on safety.</td>
<td>X</td>
</tr>
<tr>
<td><strong>Type B packages (non-fissile and fissile)</strong></td>
<td>Grade 1 Grade 2 Grade 3</td>
</tr>
<tr>
<td>All aspects contributing to the integrity of shielding, containment and criticality safety. Other aspects except where there is minimal effect on safety. Other aspects where there is minimal effect on safety.</td>
<td>X</td>
</tr>
<tr>
<td><strong>Shipments and special arrangements</strong></td>
<td>Grade 1 Grade 2 Grade 3</td>
</tr>
<tr>
<td>Management system requirements are applied according to individual features.</td>
<td>X</td>
</tr>
</tbody>
</table>

ACKNOWLEDGEMENTS

The author is thankful for the great help and support of Dr. S. Salama, Radiation protection expert (RPF-ETRR-2 Complex), Eng. Ashraf S. Kamoon, Egyptian Nuclear & Radiological Regulatory Authority (ENRRA), and Eng. A. Alaniz, INVAP SE- Argentina ) in supplying him with the needed references as well as reviewing the present document.

REFERENCES

(9) Transportation of radioactive material, department of Transportation Nuclear Regulatory Commission, Rev 0703, USNRC 2000.
Annex (1) : Radioactive material packages used in ETRR-2 facilities

- Vial (Glass or stainless steel)
- Shielding (Lead)
- Foam
- Steel can
- Overpack

- Stainless steel container
- Spacer
- Wooden box

- UN 2915

- Vial (Glass or stainless steel or plastic)
- Shielding (Lead)
- Overpack

- UN 2916
- Low dispersible radioactive material

- UN 2917
- Special form radioactive material

- All other radioactive material
- Vial (Glass or stainless steel or plastic)
- Stainless steel container
- Spacer
- Wooden box

- Special form

- Other radioactive material

- Solid
- Liquid

- Excepeted packages

- Special form
- Other forms