REGULATORY GUIDE

GENERAL TRANSPORT GUIDANCE

RG-0008

Rev 0

professionalism  integrity  value our people  excellence  teamwork  openness & transparency

UNRESTRICTED
## APPROVAL RECORD

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1 BACKGROUND

Regulations are mandatory and set down specific requirements to be upheld by the authorisation holder or an applicant for a nuclear authorisation. Guidance documents are developed to assist authorisation holders or/and applicants for authorisations in meeting the regulatory requirements. In general guidance documents have to be adhered to by the holder/applicant. Any deviation from NNR guidance has to be justified.

The object of the National Nuclear Regulator (the Regulator) is to, amongst others, establish safety standards and regulatory practices to protect the public, property and the environment against nuclear damage. As part of the mandate, the Regulator has prepared this guideline to ensure that radioactive material is transported in compliance with safety regulations, approved plans and procedures.

The document provides guidance on the regulatory requirements as contained in Part SEVEN: Safe Transportation of Radioactive Material of the draft General Nuclear Safety regulations. Due to the lengthy promulgation process for regulations, and the fact that the guidance provided is based in draft regulations, the Executive has resolved to issue the document as INTERIM guidance.

The document will be revised once the regulations in question have been promulgated and circulated to solicit stakeholder comments in accordance with the Regulators document development process.

2 PURPOSE

The purpose of the document is to provide guidance on the implementation of the NNR requirements as as set out in Part SEVEN of the draft General Nuclear Safety regulations on the Safe Transportation of Radioactive Material.

3 SCOPE

This Regulatory Guidance (RG) applies to the transport of all radioactive material, as defined in the National Nuclear Regulator Act (NNRA) within the boundaries of South Africa, or within the territorial waters of South Africa.

4 TERMS, DEFINITIONS AND ABBREVIATIONS

4.1 Terms and Definitions

In this RG any word or expression to which a meaning has been assigned in the NNRA or the Regulations promulgated in terms of the NNRA, shall have the meaning so assigned.
Additionally any word or expression to which a meaning has been assigned in the International Atomic Energy Agency (IAEA) Regulations for the Safe Transport of radioactive Material, should have the meaning so assigned, except in instances where there is a contradiction with any meaning so assigned in the NNRA or in the Regulations promulgated in terms of the NNRA. In such instances the NNRA or Regulatory meanings should take preference.

IAEA Regulations - The International Atomic Energy Agency Regulations for the Safe Transport of Radioactive Material (SSR-6), or as amended from time to time.

Packaging - The assembly of components necessary to enclose the radioactive material completely.

Package - The packaging with its radioactive contents presented for transport.

4.2 Abbreviations

IAEA : International Atomic Energy Agency
NNR : National Nuclear Regulator
NNRA : National Nuclear Regulator Act, Act 47 of 1999
RG : Regulatory Guidance Document
SSRP : Regulations in terms of section 36, read with section 47 of the National Nuclear Regulator act, 1999 (Act No. 47 of 1999), on Safety Standards and Regulatory Practices

5 GENERAL PROVISIONS

5.1 Authorisation needs

5.1.1 In cases where both the consignor and consignee are within South Africa, then both parties should be in possession of either a nuclear authorization, issued by the NNR, or of a permit issued by the Department of Health, before they may address the radioactive shipment.

5.1.2 In either case the transport should be undertaken under either the consignor’s authorisation/permit in terms of a formal agreement between the parties.

5.2 Liability for nuclear damage

5.2.1 In the event that a South African based company imports OR exports any radioactive material to OR from a foreign company (under an existing nuclear authorisation) then the following applies:

i. If the transport is done under a certificate of registration (COR) then the normal common law applies, or

ii. If done under a nuclear licence then strict liability applies with the holder of the licence being liable.
5.3 **Consignors responsibility**

5.3.1 The consignor should comply fully with the consignor responsibilities as detailed in the IAEA regulations for the Safe Transport of Radioactive Material in the Edition references in their nuclear authorisation.

6 **EXEMPTION FROM COMPLIANCE WITH THE IAEA TRANSPORT REGULATIONS**

6.1 By virtue of Paragraph 107(e) of the IAEA Regulations for the Safe Transport of Radioactive Material [4] the following radioactive transports are exempt from the need to comply with the requirements of the IAEA Regulations:

   i. Radioactive material that is an integral part of the means of transport;
   
   ii. Radioactive material moved within an establishment which is subject to appropriate safety regulations in force in the establishment and where the movement does not involve public roads or railways;
   
   iii. Radioactive material implanted or incorporated into a person or live animal for diagnosis or treatment;
   
   iv. Radioactive material in consumer products which have received regulatory approval, following their sale to the end user;
   
   v. Natural material and ores containing naturally occurring radionuclides which are either in their natural state, or have been processed for whatever purpose, provided the activity concentration of the material does not exceed the values specified in Table 2, or calculated in accordance with paragraphs 403–407 of SSR-6 [4];
   
   vi. Non-radioactive solid objects with radioactive substances present on any surfaces in quantities not in excess of the levels defined in paragraph 214 of SSR-6 [4].

6.2 Compliance with any of the above transport exemptions grants the consignor the right to transport the material as non-radioactive material. In practice this amounts to not needing to either label the shipment as radioactive, including the exclusion of Class 7 placarding, as well as not needing to document the shipment as Class 7 dangerous goods.

6.3 However this does not imply that the material is exempt from the need to comply with the NNRA. Hence the consignor should still be in possession of an NNR authorisation.

7 **CATEGORISATION OF RADIOACTIVE MATERIAL FOR TRANSPORT PURPOSES**

7.1 Regulation 4.0 of the Part SEVEN of the draft General Nuclear Safety regulations on the Safe Transportation of Radioactive Material categorizes radioactive material as either Category 1 or Category 2 radioactive material. This categorisation should not be confused with Category 1, Category 2 and Category 3 applied for radioactive sealed...
sources, as per Annex 1 of the IAEA Conduct on the Safety and Security of Radioactive Sources (Vienna 2004).

7.2 All radioactive materials which may be transported under the NNRA and not exempted should be categorised at least Category 2 radioactive material.

7.3 Since fissile material and uranium hexafluoride presents a potential criticality hazard, these materials should be categorised for transport purposes as Category 1. Uranium hexafluoride presents an additional high chemical hazard as it emits fumes of highly toxic metallic uranium and uranium fluorides when heated to decomposition, it reacts vigorously with aromatic hydrocarbons, undergoes violent reaction with water or alcohols and reacts with most metals.

8 APPLICATION FOR APPROVAL OF TRANSPORTATION

8.1 General

8.1.1 All holders and applicants for authorisations should make application prior to the first shipment for the approval of any proposed transport, or series of transports of radioactive material.

8.1.2 The application should contain a safety assessment identifying potential radiation doses likely to be incurred during all aspects of the transport operations.

8.2 Transport procedure or plan

8.2.1 A transport procedure should be compiled for the shipment and should cover, as a minimum, the following:

i. Description of the material to be transported and mode of transport. The holder submission should describe the material to be transported and the mode of transport.; and

ii. An assessment whether such material is excluded from the IAEA Transport Regulations (SSR-6) giving full justification in cases where exemption is requested.

8.2.2 Transport routes

8.2.2.1 The transport procedure or plan should contain the details and maps of the specific modes of transport and of the routes to be followed by each transport that involves radioactive material.

8.2.2.2 The name(s) of the carrier should be provided.

8.2.2.3 The name(s) of the destination(s) should be provided with an indication as to whether it is an Authorised facility, or whether the transport is between sections of the same authorised facility.

8.2.3 Controls and communication
8.2.3.1 The transport procedure or plan should contain those actions that are required by the NNR to ensure that radiation hazards are properly controlled during transportation.

8.2.4 The transport procedure should demonstrate proper application of the following:
   i. Transport index;
   ii. Radiation dose rate limits;
   iii. Contamination limits;
   iv. Activity limits;
   v. Exclusive use shipments, where appropriate; and
   vi. Separation and segregation to manage or minimise hazards to persons, property and environment during all transport operation phases.

8.3 Exemption justification

8.3.1 If an exemption is requested on the grounds of SSR-6 paragraph 107(e)v then this should be supported by an exemption calculation utilising measured nuclide data. In such a calculation it is preferable that all nuclides in the U-235, U-238 and Th-232 decay chains are measured and included in the calculation.

8.3.2 However, it is considered reasonable to exclude from the analysis:
   i. Radionuclides having half-lives less than 10 days;
   ii. All beta emitters;
   iii. Radon-222; and
   iv. The entire U-235 chain.

8.3.3 On the basis of the above assumptions, the following radionuclides should be included in the calculation for exemption:

<table>
<thead>
<tr>
<th>U-238</th>
<th>Pb-210</th>
<th>Th-230</th>
<th>Ra-226</th>
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<tbody>
<tr>
<td>Th-232</td>
<td>Pb-212</td>
<td>Th-228</td>
<td>Ra-228</td>
</tr>
</tbody>
</table>

8.3.4 If the above nuclides are the only nuclides measured, then in the exemption calculation the nuclides, following the above in the respective decay chains and not measured, should be assumed to have the same value as the above measured nuclide in that chain and this should be included in the calculation for exemption.
9 QUANTIFICATION OF DOSES FOR APPROVED TRANSPORTS

9.1 General

9.1.1 Since the transport is yet to take place, it will be acceptable for the safety assessment to be based on best estimate calculation of doses, including an uncertainty analysis and sensitivity analysis as appropriate, likely to be incurred during transport operations. Such safety assessment may be based upon data from similar, or identical shipments, if such data is available, or on dose modelling, using an accepted code, or any other methodology acceptable to the NNR.

9.1.2 In the event that the pre-shipment safety assessment is based upon acceptable best-estimates or upon acceptable modelling, the consignor should commit to undertake real-time measurements during the first transports so as to provide either a justification for, or a modification of, the initially submitted assessment.

9.1.3 The following aspects should be covered by such assessment:

i. Potential radiation dose to workers involved in either loading or unloading of the cargo;

ii. Potential radiation dose to the transport driver or other transport persons accompanying the transport;

iii. Potential radiation dose to any persons who may be required to interact with the shipment during transport (e.g. customs officials, weighbridge operators etc); and

iv. Potential radiation dose to members of the public, arising from the transport.

9.1.4 The safety assessment should address the following pathways, as appropriate:

i. External dose due to gamma radiation;

ii. Potential internal radiation dose arising from surface contamination (where applicable); and

iii. Airborne radiation dose due to particulate matter unless reduced through appropriate packaging (justification to be provided).

9.1.5 Since all transports of radioactive material would be from, or to, sites which either are authorised by the NNR, or are permitted by the Department of Health, potential radiation dose to workers involved in the preparation of the proposed transport should be addressed as part of the normal site radiation protection programme.

9.1.6 Aspects related to receiving and unloading of the shipment should be addressed by the consignee, as part of their normal site radiation protection programme. As such this does not need to be addressed in the consignor’s application for permission to transport, except in cases where the consignors workforce will be involved, or where the workers involved in the unloading operations fall under the consignors nuclear authorisation.

9.2 Potential worker dose during transport

9.2.1 The consignor should identify the “most exposed” shipment worker accompanying the transport and should provide a justification for this choice.
9.2.2 Subsequently, it should be determined that the radiation exposure of such a person, for the duration of a single shipment, is optimised.

9.2.3 Such assessment should be undertaken during the first shipment.

9.2.4 In cases where other workers accompany the shipment then the assessment should also cover radiation exposure to such workers.

9.2.5 When quantifying the dose to the most exposed shipment worker, the following aspects should be taken into account:
   i. His/her total accumulated radiation dose for the year up to the proposed transport;
   ii. The possibility that he/she may be involved in multiple shipments throughout the remainder of the year; and
   iii. Dose optimisation through worker rotation.

9.3 Potential public dose during transport

9.3.1 Should the assessment of the most exposed shipment worker indicate that they are not exposed to a radiation dose exceeding an Investigation Level, defined at 1/10 of the public dose limit, or a value of 100 μSv/a (based on the number of such shipments proposed for the year) then compliance to this Investigation Level may be used as a justification for not assessing the potential dose of the public along the proposed transport routes and involving routine or normal transport operations. However, even in this case it should be demonstrated that, as regards public dose, this potential public exposure is optimised.

9.3.2 In the event that the assessment shows the most exposed transport worker to receive a dose in excess of the Investigation Level of 100 μSv/a, despite all optimisation considerations, then a public dose assessment, covering the planned transport, should be submitted and approved by the NNR before the transport may take place.

9.3.3 The results of such assessment, together with details of steps to be taken to protect the public, or to modify the transport, based upon the assessment, should be submitted to the NNR for approval, prior to the commencement of the proposed transport.

10 RADIATION PROTECTION PROGRAMMES FOR THE TRANSPORT OF RADIOACTIVE MATERIAL

10.1 For occupational exposures less than 1 mSv in a year no formal Radiation Protection Programme need be prepared. However the responsible organisation should still undertake, and document, measures to ensure that doses are below 1 mSv per annum and that these doses are optimised.

10.2 For occupational exposures arising from transport activities, where it is assessed that the effective dose is likely to:
   i. be between 1 and 6 mSv in a year, a dose assessment programme via workplace monitoring or individual monitoring should be conducted;
ii. exceed 6 mSv in a year, individual monitoring should be conducted.

10.3 Programme documents should be available, on request, for inspection by the NNR.

10.4 When individual monitoring or workplace monitoring is conducted, appropriate records should be kept.

10.5 The following table summarises the guidance provided above:

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<th>&lt; 1 mSv/a</th>
<th>&gt;1 mSv/a but &lt; 6 mSv/a</th>
<th>&gt; 6 mSv/a</th>
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<td>Routine Workplace or Individual Monitoring</td>
<td>Individual Monitoring</td>
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11 EMERGENCY RESPONSE PLANNING AND PREPAREDNESS

11.1 The consignor should have in place an emergency response procedure or plan appropriate to the level of radiation hazard presented by the shipment.

11.2 The procedure or plan should, as appropriate, give consideration of the following aspects:

(a) A Memorandum of Agreement (MoA) established between the authorisation holder and the municipalities, provincial and national authorities to ensure the coordination of emergency response for a nuclear or radiological accident;
(b) Infrastructure for coordination and operational interfaces for emergency response between the authorisation holder and municipalities, provincial and national authorities;
(c) Organisation and staffing;
(d) Clearly define responding organisations, assign positions with sufficient numbers of qualified and trained personnel, who are able to promptly respond to notifications, mitigation, protective actions and other response actions; and
(e) Establish and document the organizational relationship and interfaces between all major responding organisations.

11.3 The emergency plan or procedure should be available to relevant municipalities, provincial and national authorities.

12 QUALITY MANAGEMENT
12.1 General

12.1.1 The Quality Management Programme should be designed in accordance with quality standards acceptable to the NNR.

12.1.2 The holder should ensure that they comply fully with the stipulations of their own procedures, as related to transport. Such compliance will, of necessity, require the implementation of a full programme of self-inspection and self-audit covering all aspects of transport of radioactive material.

12.2 Noncompliance with regulatory requirements

12.2.1 In the event of any known non-compliance with any limit or requirement of the Transport Regulations of the NNR, such non-compliance should be reported to the NNR in accordance with existing occurrence reporting mechanisms.

12.3 Resources and training

12.3.1 The holder of a nuclear authorization should identify the knowledge, skills and abilities, necessary to be able to perform all the tasks and responsibilities as required by the transport and its associated quality management programme.

12.3.2 The holder should make arrangements for the selection of personnel for training to ensure that the personnel have the requisite knowledge, skills, abilities, equipment and procedures and other arrangements to perform their assigned transport functions. The arrangements should include ongoing refresher training on an appropriate schedule and arrangements for ensuring that personnel assigned to positions with responsibilities for transport undergo the specified training.

13 PACKAGE DESIGN CERTIFICATION AND VALIDATION

13.1 General

13.1.1 For any transport of radioactive material, the packaging to be used should satisfy all requirements of SSR-6 related to such packaging design.

13.2 Approval of packaging designs

13.2.1 With regard to the use of purpose-built packaging designed to contain radioactive material for transport, where either certification or validation is required, the documentation submitted in any application for certification or validation should be as listed in Appendices 1 and 2 of this document. The more general guidance for such applications are listed here below.

13.2.2 Should the holder wish to ship fissile material as fissile excepted material, by virtue of SSR-6 paragraphs 672-679, a request for such fissile exceptance should be forwarded to the NNR for approval. Such request should carry a full justification that the package, as proposed, satisfies the requirements for fissile exceptance from SSR-6.
13.3 Packaging certification process

13.3.1 For all packaging designs requiring NNR approval, as listed above, and designed and manufactured in South Africa, the organisation wishing to use the package should apply to the NNR for Certification of the design.

13.3.2 For any packaging design under an existing certificate issued by the NNR, but where that certificate was not issued to the organisation wishing to use the design, the intended user should (under their existing authorization or under the NNRA) inform the NNR of their intention to use the particular packaging.

13.3.3 For foreign packaging designs, but designed specifically for use within South Africa (i.e. a South African-based company contracts a foreign designer), if SA is the country of first use of the design then application should be made to the NNR for certification of the design, by the organisation wishing to use the design. An exception to this rule applies in cases where the competent authority in the country of origin of the design has itself certified the design, in which case a validation should be requested from the NNR.

13.3.4 In all of the above cases, should a user intend utilizing a certified, OR validated packaging, for an inventory NOT within the envelope of the existing certification/validation, the intended user should request certification/validation of such packaging, for that inventory, from the NNR.

13.3.5 In such a case it is the obligation of the applicant to both identify where the intended inventory differs from that permitted under any existing certificate as well as to demonstrate that the intended inventory does not compromise the safety of the packaging.

13.4 Packaging design certification/validation

13.4.1 For all packaging designs requiring NNR approval, as defined above, and certified by a foreign Competent Authority (CA), and where the intention is to use the packaging within South Africa, the organisation wishing to use such design should apply to the NNR for Validation of the Design Certificate issued by the CA of the country of origin.

13.4.2 Such validation should comprise, but may not be limited to:

i. Review of the packaging Safety Analysis Report (SAR);

ii. Review of the foreign certificate issued by the competent authority of the country of origin of the design; and

iii. Issuing of a validation certificate for the use of the design within South Africa.

(See Appendix 1 and Appendix 2)

14 REFERENCES

The following references were consulted during the compilation of this document:
[4] International Atomic Energy Agency Regulations for the Safe Transport of Radioactive Material (SSR-6), or as amended from time to time.
APPENDIX 1: CHECKLIST OF DOCUMENTS TO BE SUBMITTED TO THE NNR IN SUPPORT OF AN APPLICATION FOR CERTIFICATION/VALIDATION OF A TRANSPORT CONTAINER DESIGN

The following lists the documentation to be submitted to the NNR in support of an application for certification or validation of a transport container design.

The application SHOULD include:

The complete Design Safety Report (DSR) for the package. The DSR should clearly demonstrate full compliance with the International Atomic Energy Agency Regulations for the Safe Transport of Radioactive Material as per the Edition recognised within the applicants authorisation.

In the case of demonstrating compliance to the package tests specified in the Regulations, this may either be demonstrated by actual tests or by acceptable modelling.

For applications for Validation of foreign certified packages the applicant should take note:

- The applicant SHOULD submit a Copy of the Foreign Competent Authority (CA) Certificate (in English)
- It is at the discretion of the NNR to what extent the foreign DSR will be reviewed when considering the application for Validation of the design certificate.

The DSR should include:

1. All Drawings
2. Full test results/reports, or details of alternative demonstrations of compliance.
3. Material specifications, if not given on the drawings.
4. Details of the applicable Quality Assurance programmes.
5. Details of the emergency response procedures applicable whilst the package or consignment is in SA.
6. For package designs and shipments involving fissile materials, appropriate safety information on the means of establishing compliance with the regulatory criticality safety provisions.
7. For approvals under special arrangements, details of the reasons for special arrangement and compensatory safety measures that demonstrate regulatory standards of safety are attained.
8. Provision of any necessary additional details of operational controls specific to transport in SA.

General Issues:

G.1 Submit all documents in English. Time delays may result if the NNR needs to seek translation within SA.
G.2 State the date by which Approval is required.
G.3 The date of Application should be at least 3 months in advance of the date given by which Approval is required.
G.4 If the applicant is NOT the author of the DSR then, as a Minimum, the following should be submitted as an Indication that the applicant has applied their mind to determining the degree of compliance of the DSR to the requirements of the Transport Regulations:

Independent Technical Review of the Criticality Calculation, in the case of fissile material.

In the event that the cargo intended to be carried within the package by the applicant, is not identical to what is permitted by the foreign certificate, the applicant should submit a justification clearly demonstrating that the intended cargo falls within the envelope of contents permitted by the original foreign certificate.
APPENDIX 2: MINIMUM APPROVAL PROCESS TIME REQUIRED AFTER THE COMPLETE DSR SUBMISSION FOR BOTH CERTIFICATION OR VALIDATION

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<td>Design Safety</td>
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NOTE: THE ABOVE TIMESCALES APPLY ONLY ONCE THE NNR HAS RECEIVED ALL RELEVANT REQUIRED INFORMATION AND HAS INDICATED IN WRITING THAT IT IS SATISFIED WITH THE QUALITY OF DOCUMENTS SUBMITTED. IT IS THEREFORE IN THE BEST INTERESTS OF THE APPLICANT TO ENSURE CORRECT SUBMISSIONS AT THE OUTSET.