Transport Regulation Review
Quality plan
Quality plan to implement the 2015 review process for the IAEA transport regulations

DRAFT
Quality plan to implement the 2015 review process

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Introduction

This booklet is intended as instructions for the review process for SSR-6. Each review process will start with this generic outline; however the booklet is designed to be a living document, to be updated as the cycle is progressed.

Although this booklet sets out how the process should be carried out it is important to note that it is not essential that the exact process contained in this booklet should be followed to achieve the desired outcome. For each of the review cycles the process could be varied due to changes such as to external constraints. In updating the document achieving the outcome should be the major driver.

The process of reviewing SSR-6 will make use of many standard processes (such as how to hold a TM), and so will not elaborate on the details.

One of the important distinctions between this process and others is the clear separation of review and revision. This plan focuses on review. Should a revision be required a separate plan will be initiated.
**Recommended Schedule**

The following outline schedule is set out as guidance as to the preferred times for major actions. However, many of these are subject to external constraints (for example the meeting dates for TRANSSC will be subject to room availability), and these must be considered in setting the dates.

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</table>
1. Prepare list of key issues for 2015 review

**Who is involved in this activity:**
TRANSSC Members

**What is the purpose of this activity:**
Collect feedback.

**How will this be achieved:**
This is an issue for MS.

**When should this take place:**
The process is initiated at TRANSSC 28, and will be completed to allow discussion at TRANSSC 29.

**Input required for this activity:**
None.

**Output from this activity:**
TRANSSC Member input to TRANSSC 29 on key issues for review

**Resources:**
This is an issue for MS.
2. TRANSSC 29

Who is involved in this activity:
TRANSSC Members

What is the purpose of this activity:
Develop the proposed scope for the 2015 review

How will this be achieved:
By discussing TRANSSC Member input to the meeting.

When should this take place:
During TRANSSC 29.

Input required for this activity:
TRANSSC Member views on issues important to review.

Output from this activity:
A list of proposed areas for the 2015 review to focus on.

Resources:
Time during TRANSSC meeting

NOTES
3. Initiate 120 day call for issues and proposals

Who is involved in this activity:
The Secretariat

What is the purpose of this activity:
Initiates the review process.

How will this be achieved:
By making a call for proposals using a letter to all member states, with input forms attached.

When should this take place:
The process ends with the sending of a letter and this must take place at least 5 and a half months before TRANSSC 31.

Input required for this activity:
The current status of the review and revision of regulations and guidance, along with any issues already notified to the secretariat and the status of ongoing issues carried over from previous reviews would be useful background. The list of proposed issues prepared by TRANSSC 29.

Output from this activity:
A letter to all member states with forms attached.
A clean copy of documents to be reviewed to act as a reference (Rev. 0)

Resources:
Secretariat time to produce a letter and the necessary forms, with the background material.

NOTES
Since this is a formal communication with member states clearance of the letter will be required.
The secretariat is free to provide the forms by alternative electronic means (e.g. by an input form to an electronic database).
4. Submit issues for consideration

Who is involved in this activity:
Member states.

What is the purpose of this activity:
To supply to the Secretariat a comprehensive list all of the issues related to SSR-6, SSG-26 and SSG-33.

How will this be achieved:
Member States will be responsible for the process of generating a list of issues of importance to them.
The national set of issues will be communicated to the secretariat in the standard format, using the forms provided (or any alternative specified in the letter to Member States).

When should this take place:
This must be completed two weeks prior to the deadline for making papers available to TRANSSC 31.

Input required for this activity:
The letter from the secretariat initiates the process.
The issues identified by users are also essential input.

Output from this activity:
A set of fully completed forms from each member state wishing to identify issues is delivered to the secretariat.

Resources:
Resources will vary depending upon the process adopted by each member state, but will include the standard input forms.

NOTES
Member states are expected to solicit input from appropriate people in their country, and to supply the issues on the standard forms, completing as much as possible. It is suggested that member states should provide a first quality control on the issues in a manner appropriate to their country.
5. Preparation of issue papers for TRANSSC 30

Who is involved in this activity:
The Secretariat.

What is the purpose of this activity:
To make an initial paper on major issues available to TRANSSC members from the issues supplied to the Secretariat. It will also collate any papers for the UNSCETDG of importance to transport of radioactive material.

How will this be achieved:
This may be achieved through use of a consultants meeting. The output will be by normal paper distribution means.

When should this take place:
This activity must be complete at least 2 months prior to TRANSSC 30. It should take place immediately following the close of the invitation to supply input.

Input required for this activity:
The input is the list of fully completed forms from member states and the working papers for the associated UN meeting.

Output from this activity:
The output is a consolidated set of issues suitable for use at the TRANSSC 30 meeting.

Resources:
The volume of proposals will determine the resources required, but experience suggests that a short consultants meeting may be required.
6. TRANSSC 30

Who is involved in this activity:
TRANSSC Members

What is the purpose of this activity:
This meeting has no formal input to the review, but will be utilised to discuss emerging issues.

How will this be achieved:
Discussion of Secretariat produced summary papers..

When should this take place:
During TRANSSC 30.

Input required for this activity:
TRANSSC Member views on issues identified to them.

Output from this activity:
Guidance to the secretariat in producing input for TRANSSC 31

Resources:
Time during TRANSSC meeting

NOTES
7. Preparation of issue papers for TRANSSC 31

Who is involved in this activity:
The Secretariat and appropriate experts.

What is the purpose of this activity:
To make a collated collection of issues available to TRANSSC members from the issues supplied to the Secretariat. It will also collate any papers for the UNSCETDG of importance to transport of radioactive material.

How will this be achieved:
This will normally be achieved through use of a consultants meeting. The output will be by normal paper distribution means.

When should this take place:
This activity must be complete at least 2 months prior to TRANSSC 31. It should take place immediately following the close of the invitation to supply input.

Input required for this activity:
The input is the list of fully completed forms from member states and the working papers for the associated UN meeting.

Output from this activity:
The output is a consolidated set of issues suitable for use at the TRANSSC 31 meeting.

Resources:
The volume of proposals will determine the resources required, but experience suggests that a short consultants meeting may be required.

NOTES:
The issues identified by member states should be grouped by subject where possible. This process can only be initiated when member states have supplied their issues on forms.
8. Preparation for TRANSSC 31

Who is involved in this activity:
TRANSSC members.

What is the purpose of this activity:
To ensure TRANSSC members are prepared for the meeting.

How will this be achieved:
Review the issues and other papers

When should this take place:
Prior to TRANSSC 31.

Input required for this activity:
The consolidated set of issues produced by the secretariat.

Output from this activity:
TRANSSC members are expected to generate knowledgeable opinions.

NOTES:
9. TRANSSC 31

Who is involved in this activity:
TRANSSC members.

What is the purpose of this activity:
- To decide whether a revision is required and, if so, prepare documents for further work.
- To provide advice on the progressing of outstanding issues not leading to an immediate revision.
- To review UN proposals of relevance.
- To provide reports for IAEA and UN committees.

How will this be achieved:

EXAMINE ISSUES
TRANSSC will examine the list of issues using the collated list of issues. This list will also include the issues held over from previous cycles. They will:
- Further group issues where appropriate
For each issue (or group of issues)
- Decide whether there has been an issue identified
- Decide whether the correct solution path has been identified (Regulatory Change, Guidance Change, Further Study Required, Clarification Needed) and if not what the appropriate path is
- Decide whether there is sufficient justification for resolving the issue through the chosen solution path
- Record whether a change is appropriate
- If there is a change called for, decide whether it is significant in terms of safety using the criteria for publication.

The results should be recorded on a summary results form.

If Regulatory changes are called for but no individual change passes the safety significance criteria a final check should be made to determine if the collection of the changes is significant in terms of safety using the criteria for publication.

IF THE DECISION IS TO REVISE THE DOCUMENT(S)
TRANSSC should:
- Develop a draft DPP which clearly identifies the issues which will be considered.
- Develop instructions for each issue on the standard form to clearly identify the objective of the regulatory change and any concerns over unexpected consequences.
- As part of the DPP, propose whether a new edition of the regulations is required, or an amendment or some other publication route.

IF THE DECISION IS NOT TO REVISE THE DOCUMENT(S)
TRANSSC should:
- Prepare working material based on published documents incorporating justified appropriate changes.

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REVIEW PROCESS

Secretariat should:
   • File issues for future reference.

TRANSSC will examine the list of issues derived from UN papers and give advice on them.

When should this take place:
In the 12 weeks prior to a UN meeting.

Input required for this activity:
The consolidated set of issues (produced by the secretariat).
Knowledgeable opinions of TRANSSC members.
A clean copy of documents to be reviewed (Rev. 0)

Output from this activity:
The outputs of the meeting will be:
A record of decisions on the summary record sheet.
Either a draft DPP or working material incorporating the collation of issues for consideration in future cycles.
A document suitable for transmission to UN and the CSS explaining TRANSSC views on relevant UN proposals, and a summary of issues of relevance to transport and suggestions on the process through which these might be resolved.

Resources:
Up to four staff for the duration of the meeting.

NOTES
A copy of the draft letter and input forms are included at Annex 1. The criteria for publication are included at Annex 2.
ANNEX 1

DRAFT LETTER
The Secretariat of the International Atomic Energy Agency (the Agency) draws your attention to the opportunity to provide proposals on issues or identified problems that could be considered and addressed in the 20XX Edition of the Transport Regulations, SSR-6.

The proposals should primarily reflect concepts and secondarily the details of the change to the Regulations. The Secretariat kindly requests that the completed form (attached) identifying these issues or an identified problem is returned by close of business on DUE DATE. The Secretariat will collate the list of issues and identified problems received and will prepare a Working Paper for review, discussion, comment and decision at the TRANSSC 31 meeting in October 2015. TRANSSC will assess the proposals in accordance with the approved Decision Criteria.

In anticipation of receiving your contributions we thank you for your cooperation.

The proposals for issues or identified problems with respect to application of the Transport Regulations should be sent electronically to
ANNEX 1

Issue Identified with the Regulations for the Safe Transport of Radioactive Material and Supporting Documents

This form should be used for any proposed changes to the following documents
SSR-6 Edition .......
SSG-26 Edition .......
SSG-33 Edition .......

To permit effective manipulation of data between software packages, please ensure that you maintain the .rtf or .txt format for this document.

1. Unique identification
Title (assigned by proposer)

Number (assigned by IAEA on receipt of completed form):

2. Origin
Name
Organisation
Country Code
Date (DD/MM/YY)
Address
Tel
Fax
E-mail

3. Description of issue

4. Summary of proposed solution.

5. State who is affected, Competent Authority, Nuclear Industry, Medical, Radiography, Source Industry, NORM Industry or All of these.
State how they are affected.

6. Justification of change
State expected safety benefit, (negligible, low, medium or high). Add detail as necessary.
State expected cost of implementation (negligible, low, medium or high). Add detail as necessary.

7. State existing 'regulatory' text

8. State proposed 'regulatory' text.

9. State existing 'advisory' text.

10. State proposed 'advisory' text.

11. State existing 'schedule' text.

12. State proposed 'schedule' text.

13. State transitional arrangements - If needed.

14. Comments by Reviewers (assigned by IAEA):

15. Proposal Outcome - Accepted / Rejected / Modified (assigned by IAEA):

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ANNEX 1

Guidance on Issue identification form

Instructions for use

This form should be used for any proposed changes to the following documents
SSR-6 Edition ........
SSG-26 Edition ........
SSG-33 Edition ..........
To permit effective manipulation of data between software packages, please ensure that you maintain the .rtf or .txt format for this document.

1. Unique identification
Title (assigned by proposer)
Provide a short Title to identify the Issue

Number (assigned by IAEA on receipt of completed form):

2. Origin
Name
Name of individual
Organisation
Competent Authority or organisation upon whose behalf this change is being submitted
Country Code
e.g. GB
Date (DD/MM/YY)
e.g. 30/01/06
Address
Mailing address of individual
Tel
Contact telephone number
Fax
Facsimile telephone number
E-mail
E-mail address of named contact

3. Description of issue
Describe the problem to be addressed by your proposed changes. Why do the regulations or advisory text need to be changed?
The new IAEA process relies on the identification of the Issue being addressed. This section is one of the most important on the form. It is important that you try to capture the overall issue, so rather than identify a single spelling error you might identify the issue as being “SSR-6 requires an editorial review of spelling”.

4. Summary of proposed solution.
Provide a clear statement of the main objectives - What it is you want your proposal to achieve. Try to be clear about the solution “path”. For example, are changes required to the regulations, or just to the guidance? Perhaps the first step is more study rather than a change. However, if you suggest a change to the regulations or the guidance is required it will be expected that you make a first attempt at the changes below.

5. State who is affected, Competent Authority, Nuclear Industry, Medical, Radiography, Source Industry, NORM Industry or All of these.
State how they are affected.
Changes to regulations can impact stakeholders in differing ways; some areas may suffer a disproportionate impact. List all of the stakeholders that may be affected. Other industries may be indirectly involved with RAM transport, define the perceived impact on them. E.g. carriers.

6. Justification of change
State expected safety benefit, (negligible, low, medium or high). Add detail as necessary.
How does your proposal impact on safety? Is your proposal necessary?
Could the change increase dose rates unnecessarily?

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Can your proposal impact other areas?

**State expected cost of implementation (negligible, low, medium or high). Add detail as necessary.**
There are finite resources and many millions of radioactive packages in service. The actual cost of perceived minor changes can be great in terms of training and updating your package fleet.
Estimate costs in a qualitative way.
Carefully consider and state whether there are any unintended consequences. Add detail as necessary.
Is the overall 'balance of safety' worthy of the change?

7. **State existing 'regulatory' text.**
Insert your proposed text here, it is important to be clear what the 'base' text is that you are revising. Include paragraph references.

8. **State proposed 'regulatory' text.**
Insert your proposed text here, include paragraph references. Do not use redline or strikeout.

9. **State existing 'advisory' text.**
Insert your proposed text here, it is important to be clear what the 'base' text is that you are revising. Include paragraph references.

10. **State proposed 'advisory' text.**
Your proposal may need further clarification and explanation within the advisory text. It is vital that these documents are updated in sync. Insert your proposed text here, including the appropriate paragraph reference. Do not use redline or strikeout.

11. **State existing 'schedule' text.**
Insert your proposed text here, it is important to be clear what the 'base' text is that you are revising. Include paragraph references.

12. **State proposed 'schedule' text.**
Your proposal may need further clarification and explanation within the advisory text. It is vital that these documents are updated in sync. Insert your proposed text here, including the appropriate paragraph reference. Do not use redline or strikeout.

13. **State transitional arrangements - If needed**
Regulatory changes can result in packages being designed and manufactured to previous versions of the regulations. These considerations need to be detailed through transitional arrangements.

14. **Comment by Reviewers (assigned by IAEA)**
This section will be completed by the reviewers, in full consideration of all elements of the proposal.

15. **Issue/Solution Path Outcome - Accepted / Rejected / Modified (assigned by IAEA):**
'Rejection' must be justified and this will be made available to the originator (using this form). As such it is important that sufficient detail is included in this area to inform the originator fully.
If the issue is to be 'Modified', target group or persons must be identified.
It is possible that the solution path will be modified (for example where the review group decides that changes to guidance are more appropriate than changes to regulatory text). It is important to realise that it is not the precise solution that is being accepted/rejected/modified, but it is the issue and solution path. So if there is general agreement that an issue requiring regulatory change has been identified, but that the proposed text is wrong this should still be marked as accepted.

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ANNEX 2

Criteria to Identify Proposed Changes Necessitating a New Edition of SSR-6

The following principles shall be used in evaluating proposed changes to the regulations stemming from the review cycle:

- Optimisation
- Efficiency / practicality / regulatory stability
- Compliance with dose limits
- Socio-economic considerations
- Harmonisation
- Clarification

A detailed review of each change is necessary to determine its safety importance. If a significant safety change to SSR-6 is needed to maintain and assure the safety of transport, then the change is deemed to be “sufficiently important for safety to necessitate publication as soon as possible”.

Examples of changes that may warrant a revision are:

- Consistency with other safety standards (e.g. IAEA Basic Safety Standards and UN
- Recommendations on the transport of dangerous goods
- New package and/or material type classification
- Modified test requirements
- Operational events / controls
- Changes in scope to any part of SSR-6 (e.g. definitions, A1/A2 values, transport controls)
- New requirements that invalidate designs / certificates
Questions to guide the determination if proposed changes to SSR-6 are sufficiently important to safety to necessitate publication of a new edition of SSR-6

1. Is the change or set of changes needed to maintain and assure safety?
2. Is the change or set of changes sufficiently important for safety to necessitate, publication as soon as possible?
3. Does the change or set of changes have a substantial impact on the scope of SSR-6?
4. Will the change or set of changes result in a significant change to existing transport activities or invalidate existing designs or certificates?
5. Does the change or set of changes affect the established radiation protection system or the radiological basis of SSR-6?
6. Would the change or set of changes result in a reduction, or potential reduction, in overall dose?
7. Is the change or the set of changes related to new package type or material considerations?
8. Is the change or set of changes a result of improvements in testing or analysis capabilities, or from operational experience?
9. If delay in implementation of the set of changes will result in inconsistencies with other international standards, will the existing levels of safety be maintained and assured?
10. What is the risk to safety if we delay publication?
Subsidiary Questions used to gain evidence in support of the main questions

1. Does the proposed change result in any change to the dose to workers?
   1.1. If yes does the dose increase or decrease?
   1.2. If increased is there a net benefit in terms of reduction to the dose to the public in routine, normal or accident conditions of transport?
      1.2.1. If yes are worker dose limits still complied with?
   1.3. If it decreases is there a consequent increase in the dose to the public?
      1.3.1. If yes are public dose limits still complied with?

2. Recognizing that any change to the regulations places a cost burden on the Member States and other stakeholders:
   2.1. Are the expected impacts of the change well understood?
   2.2. Will there be a financial benefit to either the Member States or other stakeholders?

3. Are the criteria used to demonstrate that the safety benefits outweigh the costs acceptable to TRANSSC?

4. Does the proposal raised by one Member State have a significant detrimental effect on another Member State or other stakeholders?

5. If the change is implemented will SSR-6 be consistent with other international standards?

6. Will the proposed change provide for increased safety of transport in routine, normal or accident conditions?

7. Will the proposed change affect the risk of an incident or accident?
   7.1. If yes is the resultant change acceptable in terms of dose and/or cost.

8. Will the proposed change affect the consequences (dose/environmental harm/disruption to the transport infrastructure) of an incident or accident?

9. Will the proposed change achieve the existing objectives with reduced effort?

10. Does the proposed change have a broad impact on the Radioactive Materials Transport (RMT) community?