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Coordination between National Regulators for the Safety and Security of International Shipments of Radioactive Materials between Member States

Stephen Whittingham
Office for Nuclear Regulation, UK

Abstract

The safety record of transporting radioactive material is remarkable; globally with tens of millions of packages transported; each year with approximately 2-3% is related to the nuclear industry. Much of this success is due to the ongoing commitment made by the IAEA and its Member States to maintain over the past 50 years the prescriptive safety regulations for the transport of radioactive material (SSR6), which is the global basis of transport regulations for radioactive material.

In the coming years there will be a significant increase in the number of shipments of packages containing radioactive material, the main contributors being:

- the medical sector, with emerging markets in developing countries;
- the nuclear industry from decommissioning activities, and,
- the revival and the emergence of nuclear power generation in several Member States.

Clearly, the challenge faced by the Competent Authority (CA) in each Member State is for them to satisfy themselves, collectively for international routes, that shipments of radioactive material comply with the transport regulations thereby achieving the internationally agreed levels of safety and security provided by the transport regulatory requirements. The most efficient and effective solution is to encourage the international coordination and collaboration between Competent Authorities responsible for the regulatory oversight of transporting radioactive material both regionally and between Member States who share international trade interests/routes. In Europe, this approach was adopted with the creation, in February 2008, of the 'European Association of Competent Authorities'. With 23 EU countries involved, the Association represents more than 80% of the overall EU territory and population.

For emerging markets in developing countries insufficient regulator resources or immature regulatory infrastructures are examples of issues to be addressed if medical treatments for the diagnosis and treatment of cancers and other humanitarian aid involving radioactive material is to be provided This paper proposes the coordination and collaboration between Competent Authorities as part of a transport model that would enable the societal needs of existing and developing markets to be met.

Coordination between National Regulators for the Safety and Security of International Shipments of Radioactive Materials between Member States

Summary

The safety record of transporting radioactive material is remarkable, even more impressive when you consider the number of packages transported; in the European Union alone over 3 million packages containing radioactive material are transported each year of which 5-10% is related to the nuclear industry.

Much of this success is due to the ongoing commitment made by the IAEA and its Member States to maintain over the past 50 years the prescriptive regulations for the transport of radioactive material (SSR 6) and its associated guidance documents. TS-R-1 (the predecessor document of SSR 6) is by far the most popular IAEA document in terms of downloads and sales with some Member States adopting them directly into their domestic legal framework whilst others adopt them due to all of the TS-R-1 requirements being incorporated into the UN Model Regulations, international Modal Regulations and Member State legislation.

In the coming years there will be a significant increase in the number of shipments of packages containing radioactive material. The main contributors to this increase will be:

- the medical sector, with emerging markets in developing countries;
- the nuclear industry from decommissioning activities, and,
- the revival and the emergence of the nuclear power generation sector in several Member States.

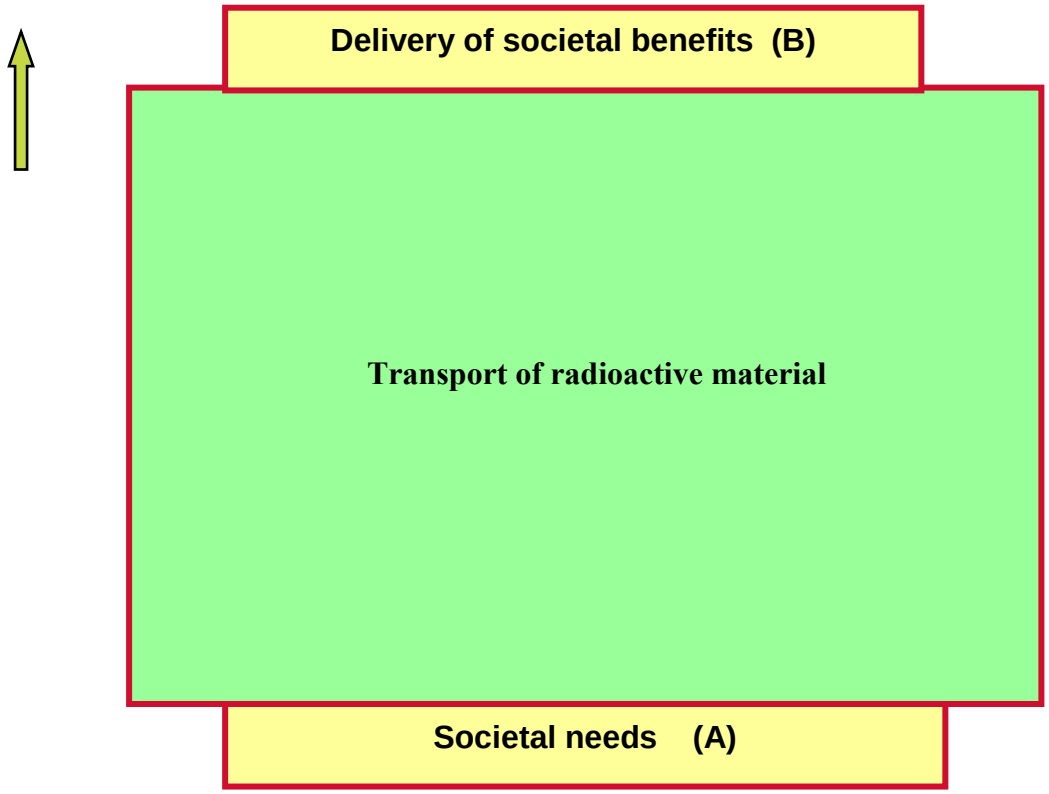
Clearly, the challenge faced by the Competent Authority (CA) in each Member State is for them to satisfy themselves, and the CA of other Member States for international shipments, that the shipments comply with the transport regulations and thereby achieve the levels of safety provided by the transport regulatory requirements.

Insufficient regulator resources or regulatory infrastructure are examples of issues faced by some Member States particularly when for example they do not have developed industry sectors relating to one or more of; nuclear power programmes; large scale radiopharmaceutical manufacture / use; naturally occurring radioactive material mining or radioactive source manufacture industries.

The most efficient and effective solution is to encourage the international coordination and cooperation between Competent Authorities responsible for the regulatory oversight of transporting radioactive material, both regionally and between Member States who share international trade interests.

In Europe, this approach was adopted with the creation, in February 2008, of the ‘European Association of Competent Authorities’. With 23 EU countries involved, the Association represents more than 80% of the overall EU territory and population.

This paper presents how the creation of regional networks between Competent Authorities at working levels can improve levels of regulatory compliance, increase regulator confidence and capabilities, promote public confidence, and reassure and increase the availability of companies who will accept to transport the material worldwide. This not only assures safety and security but also enables the future health benefits of radioactive materials in the diagnosis and treatment of cancer to be realised, particularly in developing countries.



Transport of radioactive material – From societal needs to the delivery of societal benefits

Societal needs (A)
Radioactive material (RAM) is used in many applications in our modern societies, for example, it is used to diagnose and treat illnesses such as cancer, heart disease and organ failure. 80% of surgical gloves and nearly 50% of disposable medical devices are sterilized using radioactive materials.

Often radioactive material is regarded as nuclear material and associated with the civil nuclear power programmes in many Member States.

As national regulators the language we often use relates to the technical aspects of transport package designs, shipments and security. Clearly, the challenge faced by the Competent Authority (CA) in each Member State is for them to satisfy themselves, and the CA of other Member States for international shipments, that these shipments comply with the transport regulations and thereby achieve the levels of safety and security required by international and national laws.

International transport of radioactive material is vital for the medical diagnosis and treatment of cancers and other humanitarian needs. Consequently, for some people the safe and secure delivery of radioactive material for diagnostic and treatment procedures can literally mean the difference between life and death.

The **cancer statistics for developing countries** tell their own story:

- 4 million of the 6 million deaths dues to cancer in the year 2000 occurred in developing countries lacking radiotherapy machines, in fact some parts of Africa and Asia do not carry out any diagnosis as there is little point because no treatments are available;
- 80% of cervical cancers occur in Africa, Asia and South America, with some 225 000 deaths recorded each year according to 2003 reports;
- One million new cancers are recorded each year in India (mainly throat cancer);
- Approximately 15 African nations and several other countries do not have one radiotherapy machine;
- Globally, deaths from cancer are expected to rise from 6 million in 2000, to 9 million in 2015, to 12 million by 2030.

To meet the societal needs around the world, the number of shipments of radioactive material will need to increase to meet the demands of developing health care programmes and this will involve many more Member States. We need to deliver this material and remove it at the end of its operational life within an effective framework of regulator oversight for safety and security.

An overview of transporting radioactive material (1)

The safety record of transporting radioactive material is remarkable and it is even more impressive when you consider the number of packages transported with several million being transported each year all over the world including over 3 million packages containing radioactive material transported in the European Union of which 5-10% is related to the nuclear industry.

Commercial shipping routes involve loading / unloading of goods in many Member States and the refusal of Class 7 goods by only one port of call en-route results in a denial of shipment. International shipments by sea and air are therefore problematic and the availability of routes/carriers is often fragile

Transport by air is necessary for time limited radiopharmaceuticals both for international transports between Member States and also for deliveries to remote regions within a Member State. The number of international air carriers who will accept Class 7 goods is increasing but the number of individual denials and delays is a concern. Previous work for the IAEA identified 48 stakeholder groups for the transport of radioactive material.

Regulations – transport safety and security (2)

In 1961 the IAEA created its first set of transport regulations for radioactive material. It is therefore a significant milestone achievement that the completion of the 2011 review process and the production of the 2012 edition of the TS-R-1 Regulations (SSR6), signified 50 years of the IAEA successfully managing the continued development of those regulations. We should also acknowledge the importance of the IAEA Guidance Documents (TS-G-1.1 – 1.6), which encourage common interpretation and application, of the Regulations in Member States.

The safety record is one of which everyone involved should be proud, but equally not complacent. An extremely high level of safety during transport has been achieved consistently over the past 50 years with much of this success due to the ongoing commitment made by the IAEA and its Member States to maintain the prescriptive regulations for the transport of radioactive material (SSR6, 2012) and its associated guidance documents. The IAEA has always actively involved and encouraged the support and work of many Member States to ensure that the Regulations reflect relevant and good practice and the latest developments in science and technology. The importance of this IAEA approach to manage its

work should not be underestimated as it has created and nurtured a robust transport safety and security culture in many governments, institutions and industries throughout the world.

The IAEA SSR6 transport regulations form the basis of transport regulations for radioactive material in all IAEA Member States by the adoption of the requirements into the UN Model Regulations. Indeed in some Member States, SSR6 (TS-R-1) is adopted directly into the legislative framework together with responsibilities of dutyholders being identified for each of the TS-R-1 requirements.

Transport safety

The IAEA documents related to transport safety include:

- IAEA SF-1 Safety Fundamental
- IAEA GSR Part 3 (interim) Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards
- IAEA SSR6, Regulations for the Safe Transport of Radioactive Material
  - IAEA TS-G-1.1, Advisory material
  - IAEA TS-G-1.2, Planning and preparing for emergency response
  - IAEA TS-G-1.3, Radiation protection programmes
  - IAEA TS-G-1.4, Management Systems
  - IAEA TS-G-1.5, Compliance Assurance
  - IAEA TS-G-1.6, Schedules of provisions

Transport security

SSR8 (Transport Regulations), SF-1 (Fundamental Safety Principles) and SS-115 (Basic Safety Standards) relate to transport safety but also include some reference to transport security. The Security requirements of the UN Model Regulations state basic security provisions for dangerous goods and enhanced security for 'high consequence' dangerous goods.

IAEA Nuclear Security Series No.9 takes into account UN Model Regulations; addresses the radiological concerns and hazards associated with unauthorised removal, sabotage and other malicious acts involving radioactive material

- IAEA Code of Conduct on the Safety and Security of Radioactive Sources
- IAEA Categorization of Radioactive Sources (RS-G-1.9)
- IAEA Guidance on the Import and Export of Radioactive Sources
- IAEA Nuclear Security Culture (Nuclear Security Series No. 7)
- IAEA Development, Use and maintenance of the Design Basis Threat (Nuclear Security Series No. 10)
- IAEA Preparedness and Response for a Nuclear or Radiological Emergency (GS-R-2)
- IAEA Planning and Preparing for Emergency Response to Transport Accidents Involving Radioactive Material (TS-G-1.2)

Agreements

Agreements exist between Member States for nuclear material and are set within the framework set out by the Nuclear supplier Group guidelines (INFCIRC/254) and the CPPNM (INFCIRC/275). Issues, which are the subject of ongoing dialogue, include:

- Responsibility in international waters / airspace
- Responsibilities and handover arrangements require clarity
- Cooperation in the event of theft
- Minimum levels of physical protection

Regulatory infrastructure of Member States (3)

Regulatory infrastructures in Member States can involve government, academia and institutions and for the purposes of this paper, Member States have been categorised as follows:

1. Those with civil nuclear power programmes
2. Those with developed medical and industrial sectors that use radioactive material in which,
    - •Appropriate regulatory resources and infrastructures exist to various levels and complexities
    - •Many contribute to the IAEA and other international forums
    - •Nuclear and non-nuclear regulatory infrastructures may be separated
3. Developing countries with limited regulatory resources or infrastructure
4. Developing countries with no regulatory resources or infrastructure

   Where there is little or no regulatory infrastructure,
    - A strategy of introducing a targeted and appropriate infrastructure could be adopted with the regulatory infrastructure models used in other Member States adapted to reflect specific needs. It is important that ambitions should be achievable, and, progressive as necessary over time as the infrastructures become more mature.
    - As a minimum, the initial regulatory infrastructures should ensure that inventories of RAM are established and maintained and that responsibilities for safety and security in the Regulator and industry / users are established, understood and subjected to regulator oversight

Industry compliance with regulatory requirements (4)

Compliance with transport regulations is the most important factor that affects levels of safety in transport and it is therefore essential that appropriate industry discipline (behaviours, performance) are encouraged

At a Member State level this requires an appropriate development of a safety culture, which is achieved by industry investing in appropriate levels of training, equipment and resources and adopting relevant and good practices used elsewhere.

National regulator oversight and intervention (5)

Regulator strategies for oversight and intervention contribute to the creation of safety and security cultures at a national level and therefore where there is little or no regulator resources or infrastructure this can be problematic.

The adoption of regulator oversight and intervention models used in other Member States should be adapted to reflect specific needs, be achievable, be adequately resourced and progressive over time

Future trends and challenges (6)

Trends

Over the next 20 years the number of shipments will increase as decommissioning programmes progress in several Member States, which will increase demands upon the regulator community.

The medical diagnosis and treatment of cancer will become more widely available to more Member States and as a result the number of Member States involved will increase. These health care programmes will require the development of regulatory infrastructures and oversight for transport safety and security.

The removal of orphan sources also needs to be pursued in an effective and efficient way and the relatively small numbers involved may require further cooperation to facilitate their removal in the near term.

We therefore need to speed up the development of effective regulatory infrastructures and regulatory oversight in some Member States to reflect the timescales to introduce healthcare programmes and the recovery of orphan sources.

Several Member States have ambitions to develop civil nuclear power programmes and the development of small size reactors (transportable) is intended to provide a cost effective solutions. This approach will require significant cooperation to ensure the levels of safety and security to meet the regulatory requirements are achieved.

Challenges

Financial constraints in many Member States will remain or intensify for the foreseeable future with some commentators suggesting it will take some 15-20 years to fully recover. Regulatory infrastructure and resources are limited in some Member States and security will remain an issue in some regions.

There is a need to speed up the development of effective regulatory infrastructures and regulatory oversight in some Member States to reflect the timescales in which healthcare and the recovery of orphan sources programmes can be implemented.

It should be recognised that not all Member States are able to attend IAEA meetings and benefit from interactions with other regulators and industry; to large extent they are isolated.

It is therefore to be expected that the ability to transport radioactive material in a safe and secure way is necessary to meet existing societal needs and those of future generations.

International coordination / cooperation (7)

Who has an influence on the transport process to deliver societal benefits?

The answer is simple – everyone.

There are four main groups involved in the effective delivery of the societal benefits of RAM, namely

1. IAEA – with the help of Member States, to provide transport safety and security Regulations and Requirements
2. Member States – provision of effective regulatory infrastructures including national transport safety and security regulators for regulatory oversight and intervention
3. Industry – compliance with regulatory requirements for safety and security
4. Transport workers and Public – acceptance of transport [1]

The transport of radioactive material is a coordinated process with some shipments involving many Member States. This is particularly the situation for international transport by sea, which is proving to be problematic in the context of shipping routes that often use many ports of call to increase ship utilisation and cargo carrying efficiencies. When a Member State will not accept a ship carrying radioactive material into one of its seaports, then the delivery of the radioactive material cannot take place as the radioactive cargo will often represent a very small proportion of the ships manifest and it is therefore not accepted by the carrier.

For land-locked Member States delivery has to be directly by air or to a neighbouring State by sea or air and then transported by road. Suffice to say in some parts of the world this can be problematic and sometimes impossible.

National regulators review and manage the IAEA transport regulations at an international level in a coordinated way under the stewardship of the IAEA and this has led to a mature set of regulatory requirements.

The challenges for the future will be one of providing appropriate and necessary regulator oversight in those Member States in which radioactive material is despatched, passes through in transit, or received. It is therefore proposed that national regulators should adopt an international coordinated approach to provide an appropriate level of regulatory oversight for the whole transport route.

The future model – Coordination and cooperation

Coordination / cooperation between national regulators on a regional or common interest (transport route) basis will be a key enabler.

This model is used by the IAEA for the Denial of Shipment (DoS) initiative in which regional networks of Member State appointed national focal points have been created.

There are examples of coordination / cooperation between national regulators such as:

- the formal Memorandum of Understanding between the UK and France by which each State recognises the others transport package design approval certificates without further technical evaluation being necessary;
- the joint package design safety report specification operated between the national regulators of Canada and the USA;
- the package design safety report specification written by the European Association of Competent Authorities (EACA);

[1] Previous work by the UK for the IAEA Denial of Shipment international steering (DOSISC) committee identified 48 stakeholder groups for the transport of radioactive material

- the compliance inspection guide for competent authorities written by the EACA and the joint compliance inspections carried out by the national regulators of several European Member States of international shipments of common interest.

The example in Europe is the European Association of Competent Authorities (EACA) in which:

- 23 European States participate
- Provides a forum to discuss operational issues of regulatory oversight and intervention and the development of common guidance
- Facilitates the sharing of knowledge and relevant and good practice
- Provides a basis for harmonisation and common understanding
- Creates more effective communication and networking between regulators
- Provides an understanding of what each member state does thereby creating a basis to build regulator synergies at an international level.

The above examples are related to transport safety and therefore particular attention is needed for the development of transport security aspects.

For the future, this paper proposes the adoption and development of a coordination and cooperation model between national regulators on a regional of common interest (transport route) basis to meet their transport needs. Developing Member States do no need the complex regulatory infrastructures that can be associated with nuclear or radioactive mature countries. They do need to have the confidence that they can deliver the minimum necessary to ensure the safe and secure import and export of radioactive material, therefore the coordination and cooperation provided should be appropriate and proportionate in the near term which will mature and develop over time in a controlled and appropriate way.

Worker and public confidence (8)

One of the main benefits of this coordinated / cooperative approach is that it provides a platform upon which worker and public confidence can grow.

As stated previously, earlier work for the IAEA DoS initiative identified 48 stakeholder groups for the transport of radioactive material and consequently there are many groups of workers involved in the transport operations that can have a direct influence on transport operations.

Some workers and public have genuine concerns and a variety of engagement strategies need to be considered to establish the most appropriate and effective approach.

Confidence will be a mix of appreciation and understanding which then encourages acceptance, which at best for many, will result in indifference

Delivery of societal benefits (B)

Transport is a vital enabler. A strategy of coordination and cooperation between national safety and security regulators, on a regional or common interest (transport route) basis, will enable the delivery of appropriate regulatory infrastructures on timescales to meet the needs of vital healthcare programmes that involve radioactive material.

Coordination and cooperation will not only meet future needs, it is also necessary to maintain existing, and open new, international routes that are safe, secure, effective and reliable

Conclusions

Coordination between National Regulators for the Safety and Security of International Shipments of Radioactive Materials between Member States

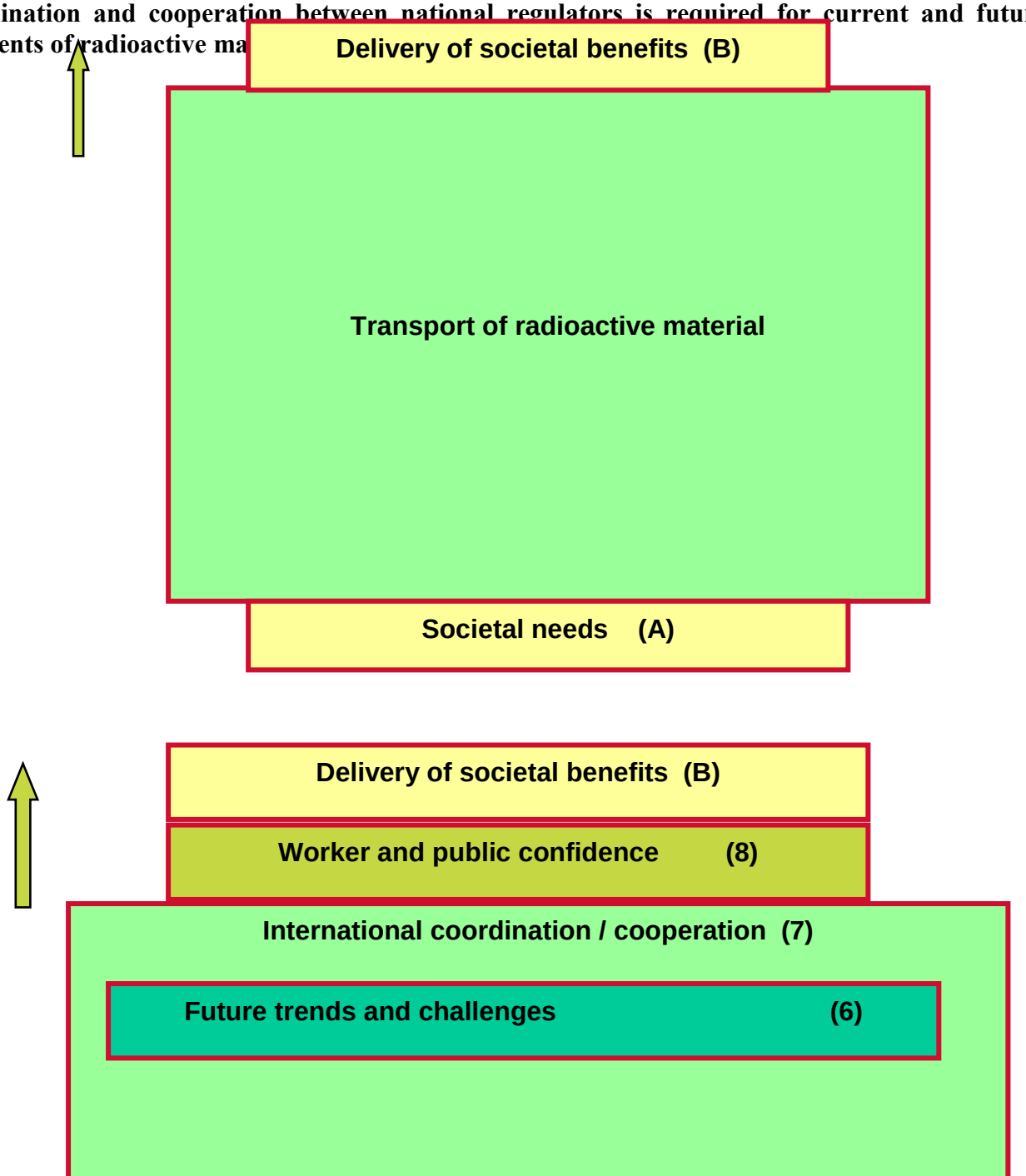
We have the transport safety and security regulations and requirements. The IAEA has developed a mature set of transport safety and security requirements that capture relevant and good practice and latest developments throughout their ongoing review process.

We have mature transport safety and security cultures in some Member States. The development and ongoing management of the IAEA regulations and recommendations has also created robust transport safety and security cultures in many Member States.

Future societal needs will mean more Member States will be involved. Timescales that reflect the societal needs for radioactive material in developing Member States to meet their healthcare and other humanitarian societal needs must be recognised

We will need to improve transport safety and security infrastructures in some Member States. We have mature transport safety and security infrastructures in some Member States and these needs to be used in a coordinated way to underpin the development of healthcare programmes in various regions around the world.

Coordination and cooperation between national regulators is required for current and future shipments of radioactive ma



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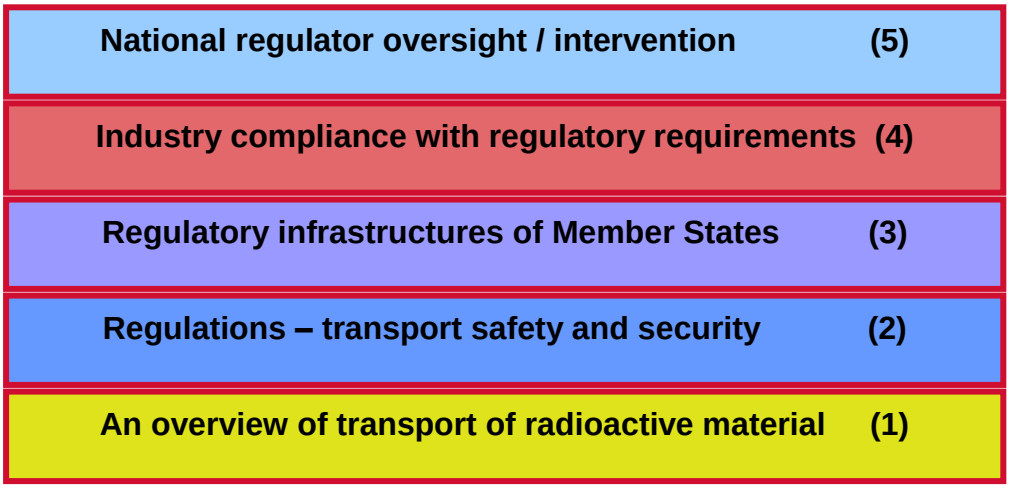

Transport of radioactive material –

From societal needs to the delivery of societal benefits