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| ONR Technical Assessment Guide  Transport Competent Authority (TCA) approvals – Human factors assessment |



ONR Technical Assessment Guide (TAG)

Transport Competent Authority (TCA) approvals – Human factors assessment

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# Introduction

1. The Office for Nuclear Regulation (ONR) is the Great Britain (GB) Competent Authority for the civil transport of Class 7 (radioactive material) dangerous goods by road, rail, and inland waterways. This statutory duty is given to ONR through ‘The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009’ (CDG09) [1] which are nuclear regulations under the ‘Energy Act 2013’ [2] for Class 7 dangerous goods.
2. CDG09 [1] transposes into GB law the international standards for transport of dangerous goods by road (ADR) [3] and rail (RID) [4], which, in turn, for class 7 dangerous goods, are based on the International Atomic Energy Agency (IAEA) Regulations for the Safe Transport of Radioactive Material (currently SSR-6, [5]). The IAEA Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material (SSG-26, [6]) supports SSR-6.
3. The purpose of these regulations, and the international agreements, is to ensure the safe transport of radioactive material internationally.   
   The regulations apply a graded approach, and the aspects of radioactive material transport involving higher hazards are regulated by a permissioning regime, in which certain designs and activities require Competent Authority approval prior to use.
4. ONR provides guidance [7] to organisations applying for Competent Authority approvals required by ADR and RID.

# Purpose and scope

1. The purpose of this Technical Assessment Guide (TAG) is to provide guidance and information to ONR inspectors in making regulatory judgements when assessing the human factors elements of transport Competent Authority approvals – in particular:

* Human-based safety claims;
* Human factors in design; and,
* The provision of information for use.

1. This TAG supports inspector assessment of applications made in accordance with the ‘Guidance for Applications for UK Competent Authority Approval’ [7].
2. The findings of the human factors assessment and the guidance in this TAG can also be used to inform dutyholder inspections.
3. As with all guidance, inspectors should use their judgment and discretion in the depth and scope to which they apply the guidance provided in this TAG. This TAG does not detail or prescribe specific methods, approaches or provide detailed technical guidance. Inspectors should use their own knowledge, experience and other applicable guidance when considering the adequacy of a dutyholder’s application.

# Relationship to relevant legislation

## The Carriage of Dangerous Goods and Transportable Pressure Equipment Regulations 2009

1. As set out above, CDG09 transposes into GB law the international standards for the transport of dangerous goods by road (ADR) [3] and rail (RID) [4]. The purpose of ADR and RID is to ensure the safe transport of radioactive material internationally. The following sections of ADR and RID are relevant to the assessment of human factors as part of Competent Authority approvals:

* Section 1.7.1.3 identifies that the carriage of dangerous goods includes: the design, manufacture, maintenance, and repair of packaging, and the preparation, consigning, loading, carriage including in transit storage, unloading and the receipt at the final destination.
* Section 1.7.2 requires that a radiation protection programme is established such that the magnitude of individual doses, the number of persons exposed and the likelihood of incurring exposure shall be kept as low as reasonably achievable.
* Section 1.7.3 requires the dutyholder to establish a management system based on international, national or other standards acceptable to the competent authority, the adequacy of which is considered as part of package approvals and inspections.
* Section 6.4.2.14 requires the manufacturers and distributors of the packaging to provide procedures to be followed to ensure that packages as presented for carriage are capable of passing the applicable performance tests.

1. Other sections of ADR and RID will be relevant for Competent Authority approvals in certain circumstances, e.g. approval of special arrangements or certain shipments (refer to ADR and RID section 5.1.5.2 for more information).

## The Ionising Radiation Regulations 2017 (IRR17)

1. The transport of radioactive material by road, rail and inland waterway in GB must also be in accordance with ‘The Ionising Radiations Regulations 2017’ (IRR17) [8], which is a relevant statutory provision of the ‘[Health and Safety at Work etc. Act 1974](https://www.legislation.gov.uk/ukpga/1974/37/contents)’ (HSWA74) [9].
2. ‘The [Health and Safety (Enforcing Authority) Regulations 1998](https://www.legislation.gov.uk/uksi/1998/494/contents/made)’ [10] and   
   ‘The [Health & Safety (Enforcing Authority for Railways and Other Guided Transport Systems) Regulations 2006](https://www.legislation.gov.uk/uksi/2006/557/made)’ [11] require ONR to enforce IRR17 in relation to the civil transport of radioactive material.
3. IRR17 includes regulations applicable to the assessment of human factors where dutyholders (acting as employers) undertake transport activities directly with ionising radiation. These regulations will be relevant for certain Competent Authority approvals (for example, shipment and special arrangement approvals) and dutyholder inspections, where human factors aspects are being considered:

* Regulation 8 (1) requires employers to make a suitable and sufficient assessment of the risk to any employee and other person for the purpose of identifying the measures the employer needs to take to restrict the exposure of that employee or other person to ionising radiation.
* Regulation 8 (3) requires that, where the assessment made shows that a radiation risk to employees or other persons exists from an identifiable radiation accident, the employer who is subject to the obligation in paragraph (1) to make the risk assessment must take all reasonably practicable steps to—

(a) prevent any such accident;

(b) limit the consequences of any accident which does occur; and

(c) provide employees with the information, instruction, training and equipment necessary to restrict their exposure to ionising radiation.

* Regulation 9 (1) requires employers to take all necessary steps to restrict so far as is reasonably practicable the extent to which its employees and other persons are exposed to ionising radiation.
* Regulation 9 (2) requires that an employer in relation to any work with ionising radiation that it undertakes must—

(a) so far as is reasonably practicable achieve the restriction of exposure to ionising radiation by means of engineering controls, design features and by the provision and use of safety features and warning devices;

(b) provide such systems of work as will, so far as is reasonably practicable, restrict the exposure to ionising radiation of employees and other persons; and

(c) where it is reasonably practicable to further restrict exposure to ionising radiation by means of personal protective equipment, provide employees or other persons with adequate and suitable personal protective equipment (including respiratory protective equipment) unless the use of personal protective equipment of a particular kind is not appropriate having regard to the nature of the work or the circumstances of the particular case.

* Regulation 9 (3) requires that employers who provide any system of work or personal protective equipment pursuant to this regulation must take all reasonable steps to ensure that it is properly used or applied as the case may be.
* Regulation 11 (1) requires employers who provide any engineering control, design feature, safety feature or warning device to meet the requirements of regulation 9 (2) (a) must ensure—

(a) that any such control, feature or device is properly maintained; and

(b) where appropriate, that thorough examinations and tests of such controls, features or devices are carried out at suitable intervals.

* Regulation 13 (1) Where an assessment made in accordance with regulation 8 shows that a radiation accident is reasonably foreseeable (having regard to the steps taken by the employer under paragraph (3) of that regulation), the employer must prepare a contingency plan designed to secure, so far as is reasonably practicable, the restriction of exposure to ionising radiation and the health and safety of persons who may be affected by such accident.
* Regulation 13 (2) An employer must ensure that—

(b) any employee under the employer's control who may be involved with or affected by arrangements in the plan has been given suitable and sufficient instructions and where appropriate issued with suitable dosemeters or other devices;

* Regulation 6 Where work with ionising radiation undertaken by one employer is likely to give rise to the exposure to ionising radiation of the employee of another employer, the employers concerned must co-operate by the exchange of information or otherwise to the extent necessary to ensure that each such employer—

(a) has access to information on the possible exposure of their employees to ionising radiation

1. IRR17 also includes regulations applicable for human factors for Competent Authority approvals where the dutyholder is acting as a designer, manufacturer, importer or supplier of articles for use in work with ionising radiation. This includes:

* Regulation 32 (1) requires manufacturers etc. of articles for use in work with ionising radiation to comply with section 6(1) of the HSWA74 so that any duty imposed on any person by that subsection includes a duty to ensure that any such article is so designed and constructed as to restrict so far as is reasonably practicable the extent to which employees and other persons are or are likely to be exposed to ionising radiation.

1. HSWA74 states:

* 6(1) It shall be the duty of any person who designs, manufactures, imports or supplies any article for use at work or any article of fairground equipment—

(a) to ensure, so far as is reasonably practicable, that the article is so designed and constructed that it will be safe and without risks to health at all times when it is being set, used, cleaned or maintained by a person at work;

(b) to carry out or arrange for the carrying out of such testing and examination as may be necessary for the performance of the duty imposed on him by the preceding paragraph;

(c) to take such steps as are necessary to secure that persons supplied by that person with the article are provided with adequate information about the use for which the article is designed or has been tested and about any conditions necessary to ensure that it will be safe and without risks to health at all such times as are mentioned in paragraph (a) above and when it is being dismantled or disposed of; and

(d) to take such steps as are necessary to secure, so far as is reasonably practicable, that persons so supplied are provided with all such revisions of information provided to them by virtue of the preceding paragraph as are necessary by reason of its becoming known that anything gives rise to a serious risk to health or safety.

# Relationship to IAEA safety standards and guides and other international standards

1. For Class 7 dangerous goods, ADR [3] and RID [4] are based on the IAEA Regulations for the Safe Transport of Radioactive Material (currently SSR-6, [5]) and so SSR-6 is not discussed further within this section (refer instead to section ‎3.1).
2. Beyond SSR-6, The IAEA identifies the importance of considering human factors to prevent human and organisational failures in Principle 3 of the Fundamental Safety Principles [12].
3. Principle 3 cascades into IAEA’s guidance on the Safety Assessment for Facilities and Activities General Safety Requirements (GSR) Part 4 [13].   
   The transport of radioactive material is specifically identified as an activity to which GSR Part 4 applies. GSR Part 4 identifies two requirements that support the assessment of human factors in Competent Authority approvals. These are:

* Requirement 7 expects:

All safety functions associated with a facility or activity shall be specified and assessed, which includes any human actions necessary to ensure the safety of the facility or activity.

* Requirement 11 expects:

Human interactions within the facility or activity shall be addressed in the safety assessment, and it shall be determined whether the procedures and safety measures that are provided for all normal operational activities, in particular those that are necessary for implementation of the operational limits and conditions, and those that are required for responding to anticipated operational occurrences and to accident conditions, ensure an adequate level of safety.

1. The supporting paragraphs to Requirement 11 state:

* Whenever the safety of facilities and activities depends on human actions, including actions taken in accident conditions, human interactions with the facility or activity shall be assessed.
* It shall be evaluated in the safety assessment whether personnel competences, the associated training programmes and the specified minimum staffing levels for maintaining safety are adequate.
* It shall be determined in the safety assessment whether requirements relating to human factors were addressed in the design and operation of a facility or in the way in which an activity is conducted. This includes those human factors relating to ergonomic design in all areas and to human–machine interfaces where activities are carried out.

## Other international standards

1. The following international standards are also relevant:

* BE EN IEC/IEEE 82079-1:2020 Preparation of information for use (instructions for use) of products [14].

# Advice to inspectors

1. Section 5.1.5.2 of ADR [3] and RID [4] detail where competent authority approval is required. Dutyholders are required to meet the relevant clauses of ADR and RID, to support the approval required. The inspector should proportionately consider the relevance and applicability of the following guidance to the type of approval being requested.
2. During assessment of a transport application for Competent Authority approval, ONR will assess the associated safety case. The role of the inspector considering human factors aspects during the Competent Authority assessment is threefold:

* Determine whether the dutyholder has developed a suitable and sufficient safety case that systematically identifies the administrative controls and human actions necessary to ensure safe configuration of the transport package and can demonstrate these are achievable.
* Determine whether the package design accounts for human capabilities and enables reliable human performance during use and maintenance.
* Determine whether the information provided by an applicant as part of the approval supports reliable use and maintenance of the packaging by the user.

1. The following provides additional guidance on each of the three criteria, to enable inspectors to assess the human factors elements during the approval.

## Human-based safety claims

1. The dutyholder’s submission should demonstrate that it has systematically identified and analysed all operational, administrative, and managerial requirements necessary to ensure safe configuration of the package for transport. This is necessary to ensure that the risk arising from using the packaging has been reduced so far as is reasonably practicable.
2. When considering the extent to which this has been achieved, the inspector should consider whether the dutyholder has:

* Conducted a suitable and sufficient hazard and fault analysis to identify the safety functions required to ensure safe configuration of the package for transport.
* Undertaken a systematic analysis (for example, undertaken a task breakdown, engineering analysis or function analysis) of the way in which the package will be used and maintained, including the operational conditions that may be encountered, to identify the human actions that have safety importance. These could include:
  + Those actions which result in an immediate consequence if performed incorrectly (for example, removing a shielded flask lid in an unshielded area).
  + Those actions which prevent a consequence being realised in the future such as:
    - During operation (for example, undertaking a leak test, to confirm the package containment is adequate).
    - During maintenance (for example, the inspection and replacement of safety important components).
* Identified the administrative or managerial controls necessary to deliver all relevant safety functions and/or reduce the probability that safety important human actions are completed incorrectly (for example, leak test pass criteria, lid bolt torque settings, content limits, radiological monitoring or independent checking).
* Undertaken proportionate analysis of these safety important actions and administrative controls to understand the potential for errors[[1]](#footnote-2), violations[[2]](#footnote-3) and dependencies[[3]](#footnote-4) and any mitigations necessary to reduce their likelihood.
* Defined, in the safety case, the administrative and managerial controls in such a way that they can be appropriately implemented and complied with. The wording of administrative or managerial control should wherever possible be simple, with the tasks not complex and include:
  + **What** needs to be achieved;
  + **When** the control should be implemented, taking into account what prompts the activity to commence and the timescale it should be completed in; and,
  + **How** the activity must be completed, including the equipment that should be used and any criteria that should be achieved (for example, lid bolt torque) to ensure compliance with the control.
  + The dutyholder should also specify **where** the activity needs to be completed, and **by whom**, if these criteria are necessary to ensure the safety function is adequately achieved.
* Provided proportionate evidence that justifies the achievability of the safety important actions, and administrative and managerial controls.
* Proportionately accounted for any operational experience gained during the historic use of the package or from other packages of a similar type or construction.

## Human factors in design

1. The dutyholder should proportionately integrate human factors principles into the physical design of the package and the safety case (also referred to as the Package Design Safety Report).
2. The application of human factors ensures the design and operation of the packaging takes appropriate account of the capabilities of the human operator, optimising human performance and minimising the potential for human error. The inspector should proportionately consider whether the dutyholder:

* Implemented a suitable and proportionate process to account for human factors in the design of the packaging and the development of the safety case, including the following aspects:
  + Provision of guidance to package designers to guide effective consideration of the human.
  + Positive confirmation at suitable points through the design process that human factors has been effectively integrated. One way to achieve this is through including human factors requirements within the gated design process.
  + Demonstration that human physiological characteristics (such as reach, strength, sight, etc.) and human psychological characteristics (such as perception, attention, decision making, etc.) have been used to inform the design. These can be used to ensure:
    - the design of the packaging and its operation is compatible with the task requirements, user characteristics and their expectations.
    - the design of the packaging provides sufficient and unambiguous information to support the operator in maintaining situational awareness in the completion of safety important activities.
    - the operator receives clear and unambiguous feedback when safety important tasks or administrative controls have been successfully completed.
    - the design of the packaging and the completion of safety important tasks takes account of any requirements to wear personal protective equipment and the effect this has on visibility, reach, dexterity, etc.

## The provision of information for use

1. The dutyholder is expected to have an adequate system in place to manage the operation, maintenance, and inspection of the package. Specifically, the dutyholder is expected to provide adequate information to the user to support the safe operation and maintenance of the package.
2. The provision of adequate information includes the provision of instructions and the identification of any additional training requirements. These aspects are essential for providing the user of the package with information about safety important tasks and the required administrative and managerial controls, to ensure packages are safely configured for transport.
3. The inspector should consider whether:

* The dutyholder has a process, based on relevant standards, which enables the development, update and testing of supporting procedures and the identification of training requirements.
* The information provided to end users supports the safe use and maintenance of the package. The information should:
  + Be clear, concise and comprehensible, using active language[[4]](#footnote-5) to describe task steps.
  + Provide illustrations (where necessary) to support clarity and achievement of the task step.
  + Provide specific information and clear success criteria needed to complete an action/task step (for example, required torque, required pressure).
  + Provide a single action per task step.
* The administrative and managerial controls and the associated safety related activities, which the user needs to carry out, are clearly identified in the instructions. Any tasks supporting the safety related activities should also be clearly and concisely set out.
* The instructions clearly identify where any residual hazards reside and provide clear warnings and cautions that precede the residual hazards.

1. Where the dutyholder directly undertakes transport activities with ionising radiation, the inspector should consider whether the dutyholder has established and implemented adequate control of work arrangements including the provision of training, instructions, equipment and supervising activities, to ensure that the risk is reduced so far as is reasonably practicable (SFAIRP). Broader human factors ONR guidance including ‘Training and Assuring Personnel Competence’ [15], ‘Staffing levels and Task Organisation’ [16] and ‘Control and Supervision of Operations’ [17] should be considered and proportionately applied where applicable.
2. Additionally, inspectors should proportionately consider the guidance provided within “Preparation of information for use (instructions for use) of products” [14], when assessing instructions provided to support package operations.

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| [14] | BSI, “BS EN IEC/IEEE 82079‑1:2020 - Preparation of information for use (instructions for use) of products,” 2020. |
| [15] | ONR, “NS-TAST-GD-027 - Training and Assuring Personnel Competence”. |
| [16] | ONR, “NS-TAST-GD-061 - Staffing Levels and Task Organisation”. |
| [17] | ONR, “NS-INSP-GD-026 - Control and Supervision of Operations”. |

# Glossary and abbreviations

ADR The Agreement concerning the International Carriage of Dangerous Goods by Road

CDG09 The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009

GB Great Britain

GSR General Safety Requirement

HSWA74 [Health and Safety at Work etc. Act 1974](https://www.legislation.gov.uk/ukpga/1974/37/contents)

IAEA International Atomic Energy Agency

IRR17 Ionising Radiations Regulations 2017

ONR Office for Nuclear Regulation

RID The Regulation concerning the International Carriage of Dangerous Goods by Rail

SFAIRP So far as is reasonably practicable

SSR Safety Standards Regulation

TAG Technical Assessment Guides

1. A human error is an action or decision which was not intended, which involved a deviation from an accepted standard. [↑](#footnote-ref-2)
2. A violation is a deliberate, but not malicious, deviation from a defined rule, procedure or standard. [↑](#footnote-ref-3)
3. Dependency is the degree to which one erroneous action can impact the reliability of subsequent actions, or where common factors can impact the reliability of several actions within a single fault progression. [↑](#footnote-ref-4)
4. Active language expresses the task requirement in the user’s voice, for example, “install the seven m32 lid bolts”. [↑](#footnote-ref-5)