|  |
| --- |
|  |
| ONR Project assessment report  PR-01788 - Permissioning assessment of transport package design 2773A |



ONR Project assessment report

**Project name**: PR-01788 GB/2773A/B(U) Permission

**Report title**: PR-01788 - Permissioning assessment of transport package design 2773A

**Dutyholder/Applicant**: Croft Associates Ltd

**Authored by**:

**Report issue no**.: 1

**Publication date**: May 2025

**Document ID**: ONRW-2019369590-16038

Circulation list (latest issue)

|  |  |  |
| --- | --- | --- |
| Organisation | Recipient | Date report sent |
| ONR |  |  |
| Croft Associates Ltd |  |  |

© Office for Nuclear Regulation, [2025]

For published documents, the electronic copy on the ONR website remains the most current publicly available version and copying or printing renders this document uncontrolled. If you wish to reuse this information visit [www.onr.org.uk/copyright](http://www.onr.org.uk/copyright) for details.

# Executive summary

Croft Associates Ltd (Croft) has requested that the Office for Nuclear Regulation (ONR being the Great Britain competent authority for the transport of Class 7 dangerous goods by road and rail) approve (by renewing) the extant transport package design certificate GB/2773A/B(U) Rev.10. This report presents the ONR assessment findings and regulatory decision supporting the 2773A transport package design permissioning activity.

The 2773A package design has been used to transport cobalt-60 sealed sources since the 1990s. Sealed sources are consigned in Canada and Sweden and transported worldwide for use in Elekta AB (Elekta) gamma knife units – within Great Britain they are used in ten Elekta cancer treatment facilities. ONR previously renewed this package design in April 2021. Since then, we have approved two modifications to the design.

The applicant has made several changes since the last ONR approval. Canadian Nuclear Laboratories (CNL) no longer use this package – documentation has been revised to reflect this, and the cobalt-60 activity limit has been reduced from that required by CNL (1100 TBq) to the maximum activity required by Elekta (488.4 TBq). The operating and maintenance instructions have been revised in accordance with these changes. Several other revisions to documents have been made - none of these have a material impact on the package design.

ONR has undertaken targeted and proportionate mechanical engineering and radiation shielding assessments of the safety submission, focusing on the changes to the package design safety report. No regulatory queries were raised and both assessments recommended approval. The ONR Transport Competent Authority (TCA) undertook a management system intervention of Croft in September 2022 – the intervention outcome supports the design approval.

Based on the assessment activities undertaken during this permissioning activity and the intervention in 2022, ONR is satisfied that the applicant has demonstrated that the 2773A transport package design is compliant with the relevant regulatory design requirements.

The project inspector recommended that the ONR TCA Head of Regulation approves certificate of approval GB/2773A/B(U) (Rev.11) for a duration of 5 years.

Table 1: List of abbreviations.

|  |  |
| --- | --- |
| Term/Acronym | Description |
| CA | Competent Authority |
| CNL | Canadian National Laboratory |
| GB | Great Britain |
| IAEA | International Atomic Energy Agency |
| ONR | Office for Nuclear Regulation |
| PAR | Project Assessment Report |
| PDSR | Package Design Safety Report |
| PI | Project Inspector |
| SSR | (IAEA) Specific Safety Requirements |
| SNAB | Studsvik Nuclear AB |
| TCA | Transport Competent Authority |
| TISAF | Thermal Insulating and Shock Absorbing Foam |
| TRANSSC | Transport Safety Standards Committee |
| UK | United Kingdom |

Table of contents

[Executive summary 3](#_Toc198738609)

[1. Permission requested 6](#_Toc198738610)

[2. Background 6](#_Toc198738611)

[3. Assessment and inspection work carried out by ONR in consideration of this request 7](#_Toc198738612)

[3.1. Radiation shielding assessment (ref. [4]) 7](#_Toc198738613)

[3.2. Engineering assessment (ref. [5]) 8](#_Toc198738614)

[3.3. Project inspector review 8](#_Toc198738615)

[4. Matters arising from ONR’s work 9](#_Toc198738616)

[5. Conclusions 9](#_Toc198738617)

[6. Recommendations 9](#_Toc198738618)

[References 10](#_Toc198738619)

# 

# Permission requested

1. Croft Associates Ltd (Croft – the applicant) has submitted an [application](https://prodonrgov.sharepoint.com/can_permissioning/Forms/AllItems.aspx?FolderCTID=0x0120003BC50A0F7FA7F74DBFD9895CD3139263&id=%2Fcan%5Fpermissioning%2FPR%2D01788%2FGB2773A%20Renewal%20Request%2025%2D09%2D24%2Epdf&parent=%2Fcan%5Fpermissioning%2FPR%2D01788) (ref. [1]) for renewal of transport package design 2773A, currently certified as [GB/2773A/B(U) (Rev.10)](https://prodonrgov.sharepoint.com/can_transportcertificate/GB-2773-_DB5C17EA49E4ED1188476045BD0E7A28/Certificate%20-%20GB%202773A%20B%28U%29%20%28Rev%2010%29.pdf) (ref. [2]) for transport by road, rail, air and sea.

# Background

1. The 2773A package design is approved to transport cobalt-60 sealed sources to cancer treatment facilities across the world. The package activity limit under Rev. 10 of the approval is 1100 TBq.
2. Special form sealed sources are manufactured by Nordion Inc. (Nordion) in Canada and Studsvik Nuclear AB (SNAB) in Sweden. These are transported to ten treatment centres in the UK – sources are installed into Elekta AB (Elekta) gamma knives for patient radiotherapy treatment. Redundant sources are returned to Nordion and SNAB.
3. Elekta is the owner of the cobalt-60 sources and packages. Elekta work with consignors, carriers and consignees to transport this package internationally and within the UK. Hazmat Logistics Ltd is the road carrier within the UK.
4. The package has had competent authority approval since the 1990s. A 1-year extension was issued in June 2020 to allow Croft time to make necessary changes to their risk assessment and operating instructions. The package was subsequently approved for a further 4-years in June 2021. Since the last periodic renewal, ONR have approved two modifications – one was to allow an outlier package to have a temporary extension to its maintenance period due to shipping delays during the COVID pandemic (modification CN072) and the second was to introduce a third variant of the Elekta special form capsule (modification CN073).
5. The package design consists of an inner lead shielded flask (2774) under a layer of stainless steel, encased by a cylindrical steel outer casket (2773), designed to shield gamma sources. These are separated by Thermally Insulated Shock Absorbing Foam (TISAF). Further shock protection is provided by the aluminium honeycomb within the outer casket.
6. The applicant has made several minor changes since the last renewal – these are recorded in a [periodic design review](https://prodonrgov.sharepoint.com/can_permissioning/Forms/AllItems.aspx?id=%2Fcan%5Fpermissioning%2FPR%2D01788%2FAppendix%20F%20%2D%20Technical%20Reports%20in%20DSR%2FCTR%202024%2D06%2DIssue%20A%2Epdf&parent=%2Fcan%5Fpermissioning%2FPR%2D01788%2FAppendix%20F%20%2D%20Technical%20Reports%20in%20DSR) (ref. [3]) - the key ones are summarised below:

* Canadian Nuclear Laboratories (CNL) no longer use the 2773A package design - radioactive content and furniture relating to their usage has been removed from the PDSR and the operating and maintenance instructions have been revised to reflect this.
* The design life procedure has been updated to reflect current Croft standards and International Atomic Energy Agency (IAEA) Transport Safety Standards Committee (TRANSSC) ageing guidelines.
* Improvements to documents including serviceability checks and the risk assessment, based on learning from experience, have been made.
* Tie-down stress calculations have been updated due to the withdrawal of British Standard BS 2573-1: 1983. This was superseded by the British Standard implementation of a European Standard.

# Assessment and inspection work carried out by ONR in consideration of this request

1. In accordance with the approved regulatory permissioning strategy, we have carried out proportionate and targeted assessments, focusing on the changes made to the package design safety report (PDSR) since the previous periodic renewal in 2021.
2. [Radiation shielding](https://prodonrgov.sharepoint.com/:w:/r/_layouts/15/Doc.aspx?sourcedoc=%7B01D1CEAB-1EC4-4C48-B334-D1543D6BDB90%7D&file=2773%20Shielding.docx&action=view&mobileredirect=true) (ref. [4]) and [mechanical engineering](https://prodonrgov.sharepoint.com/:w:/r/_layouts/15/Doc.aspx?sourcedoc=%7B28CDA972-52B2-4B06-BA0F-983A9EE17D25%7D&file=AR%2001610%20%20GB-2773AB(U)%20Renewal%20(PR%2001788)%20-%20Engineering%20Assessment%20Report%20%2B%20PR%20signature.docx&action=view&mobileredirect=true) (ref. [5]) assessments were undertaken. We considered human factors – a detailed human factors assessment (ref. [6]) was undertaken during the 2021 approval. There is no requirement to repeat this assessment due to the minor design changes in this submission. I have considered changes to the risk assessment and operating instructions in relation to human factors. No criticality assessment is required as the package does not contain fissile material.
3. Inspection activities are not required to support this approval due to: the hazard reduction (in terms of total activity transported); minor changes to the package design since the 2021 renewal; and, our 2022 green rated [inspection](https://wired.crm11.dynamics.com/main.aspx?appid=58b7bb57-c806-ec11-b6e5-00224841dad4&pagetype=entityrecord&etn=can_inspection&id=76761f84-bcba-4e20-bba1-3574425139e8) (ref. [7]) of Croft.

## Radiation shielding assessment (ref. [4])

1. Our radiation shielding assessment focused on the design changes that impact external dose rates – from a safety perspective the risk has been reduced due to the reduction in package users and reduction in package hazard (i.e. a lower activity limit).
2. Due to the significance of the design changes, and in accordance with our regulatory guidance, we produced a radiation shielding assessment note summarising the assessment and conclusions.
3. There have been no material changes to the package design that would invalidate our previous radiation shielding assessment (ref. [8]) undertaken to support the 2020 extension.
4. No regulatory queries were raised during the assessment. External dose rates are well within the regulatory limits under routine conditions of transport. The package design is also compliant with normal and accident condition dose rate requirements.
5. We concluded that the design meets the requirements of SSR-6 (ref. [9]) from a radiation shielding perspective and recommended approval for a period of 5 years.

## Engineering assessment (ref. [5])

1. Our mechanical engineering assessment focused on the periodic design review – this review identified changes to the design since our 2021 approval. We sampled the: dutyholder’s operating and maintenance instructions; revised ageing assessment; revised casket manufacturing specification; revised leak test procedure; and revised tie-down assessment.
2. No regulatory queries were raised during the assessment. Due to the significance of the design changes, and in accordance with our regulatory guidance, we produced an assessment note summarising the assessment and conclusions.
3. We concluded that the package should be approved from a mechanical engineering perspective and that the approval should exclude casket design 2773 serial numbers 6 and 11 due to the traceability of maintenance records.

## Project inspector review

1. I reviewed the revised 2773A risk assessment, the operating instruction and the relationship between both – improvements have been made since the last ONR approval based on learning from experience. I considered the risk assessment and operating instruction to be adequate.
2. I raised three regulatory queries relating to the loading arrangements of the special form capsules during consignment and the impact on dose accrual. Croft provided acceptable responses.
3. Croft do not have maintenance records pertaining to the packages used domestically in Japan. As such, casket design number 2773 serial numbers 6 and 11 are excluded from the approval. Additionally (and for the same reason), the inner flask design 2774 serial numbers 6 and 8 are also excluded from this approval.

# Matters arising from ONR’s work

1. None.

# Conclusions

1. Based on the assessment activities we have undertaken, and the Croft intervention referred to in paragraph 10, I am satisfied that the applicant has demonstrated that the 2773A transport package design is compliant with the relevant regulatory design requirements.

# Recommendations

1. I recommend that the ONR Transport Competent Authority Head of Regulation approves certificate of approval GB/2773A/B(U) (Rev.11) for a duration of 5 years.

# References

|  |  |
| --- | --- |
| [1] | ONRW-2019369590-13321, GB2773A B(U) Renewal. |
| [2] | Certificate of Approval GB/2773A/B(U) (Rev.10). |
| [3] | CTR 2024/06 Issue A, SAFSHIELD GB/2773A Periodic Design Review. |
| [4] | ONRW-2126615823-6912, Radiation Protection – Shielding / Dose Rate Assessment - GB/2773A/B(U) Renewal. |
| [5] | ONRW-2126615823-5863, Engineering Assessment Note - Application for renewal of GB/2773A/B(U). |
| [6] | Note for the record: Croft Associates Ltd. GB/2773A package renewal Human Factors review in support of the Safety Case Requirements Assessment, CM9 2020/174462. |
| [7] | IR-51997, CROFT - Transport - Inspection ID: 51997. |
| [8] | CM9 2020/166582, Application for Renewal of GB/2773A/B(U)-96 Certificate of Approval Renewal. |
| [9] | IAEA Safety Standards Series No. SSR-6 (Rev.1) Regulations for the Safe Transport of Radioactive Material 2018 Edition. |