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| ONR Project Assessment Report  Assessment of Modification CN073 to GB Competent Authority Approval GB/2773A/B(U) |



ONR Project Assessment Report

Project Name: Modification of SAFSHIELD Package Design Approval, PR-01250

Report Title: Assessment of Modification CN073 to GB Competent Authority Approval GB/2773A/B(U)

Dutyholder/Applicant: Croft Associates Ltd.

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# Executive Summary

Croft Associates Ltd. has applied to the Office for Nuclear Regulation (ONR) for approval of Modification CN073 to the SAFSHIELD package design [1, 2], which is effected by the extant GB/2773A/B(U) certificate. This modification application covers the addition of an updated special form Co-60 capsule design with minor dimensional changes from those already assessed by ONR and included on the extant certificate of approval.

ONR has undertaken a proportionate and targeted assessment of the modification request, covering:

* the minor changes in special form capsule design;
* a review of the previous full renewal to confirm that there are no outstanding issues relating to that approval; and
* a review of operational experience and any relevant transport incidents.

On the basis of this assessment, I recommend that ONR should approve Modification CN073 and issue a revised certificate of approval GB/2773A/B(U) accordingly.

# List of Abbreviations

ADR Agreement Concerning the International Carriage of Dangerous Goods by Road

CA Competent Authority

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

CoA Certificate of Approval

GB Great Britain

IAEA International Atomic Energy Agency

ICAO International Civil Aviation Organization

IMDG International Maritime Dangerous Goods Code

ONR Office for Nuclear Regulation

PAR Project Assessment Report

PDSR Package Design Safety Report

RID Regulations Concerning the International Carriage of Dangerous Goods by Rail

SNAB Studsvik Nuclear AB

SSG (IAEA) Specific Safety Guide

SSR (IAEA) Specific Safety Requirements

UK United Kingdom

WIReD (ONR) Well Informed Regulatory Decisions

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# Permission Requested

1. Croft Associates Ltd. has applied to the Office for Nuclear Regulation (ONR) as the Great Britain (GB) Competent Authority (CA) for a modification to the SAFSHIELD package design approval [1, 2], which is effected by the extant GB/2773A/B(U) certificate of approval (CoA) [3].

# Background

1. ONR is the GB CA for the civil inland surface transport of Class 7 dangerous goods. This statutory duty is given to ONR through The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (CDG) [4]. CDG (as they apply to Class 7 dangerous goods) are both Relevant Statutory Provisions and Applicable Provisions of The Energy Act [5]. In accordance with Agency Agreements (legal documents used to transfer statutory responsibilities between bodies) [6, 7, 8, 9], ONR also acts on behalf of other civilian United Kingdom (UK) CAs in cases where CA approval of a package design is required, namely:

* the Competent Authority of the United Kingdom of Great Britain and Northern Ireland in respect of sea transport, being the Secretary of State for Transport including the Maritime and Coastguard Agency;
* the Competent Authority of the United Kingdom of Great Britain and Northern Ireland in respect of air transport, being the Civil Aviation Authority; and
* the Competent Authority of Northern Ireland in respect of road transport, being the Department of Agriculture, Environment and Rural Affairs - Northern Ireland.

1. CDG [4] (and the Northern Ireland equivalent [10]) transpose into UK law the international standards ADR [11] and RID [12] for transport of dangerous goods by road and rail, respectively.
2. For transport of dangerous goods by sea, the international requirements are specified in the International Maritime Dangerous Goods (IMDG) Code [13] and are implemented in the UK by The Merchant Shipping Act 1995 [14] and The Merchant Shipping (Dangerous Goods and Marine Pollutants) Regulations 1997 [15].
3. For transport of dangerous goods by air, the international requirements are specified in the International Civil Aviation Organization (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air [16] and are implemented in the UK by The Air Navigation Order 2016 [17] and The Air Navigation (Dangerous Goods) Regulations 2002 [18].
4. The above modal regulations (ADR, RID, IMDG Code and ICAO Technical Instructions)[[1]](#footnote-2), are based on the International Atomic Energy Agency (IAEA) Regulations for the Safe Transport of Radioactive Material, currently SSR-6 (2018 Edition) [19] supported by the advisory material in SSG-26 [20].
5. The SAFSHIELD package design is intended for the shipment of high-activity special form and sealed solid Co-60 sources. These are used in gamma knife radiotherapy applications for cancer treatment.
6. ONR has given package design approval for the SAFSHIELD on a number of previous occasions, with the most recent full package design approval renewal completed in 2020.

# Assessment Work Carried out by ONR in Consideration of this Request

1. This permission relates to an application for a modification to the SAFSHIELD package design approval. This has been assessed in accordance with ONR’s trnasport permissioning guidance [21] and the agreed permissioning strategy [22].
2. This modification relates to the addition of an updated special form capsule design to the permitted contents. This capsule design has minor dimensional changes from the previously approved special form capsules used by Elekta as an operator of the GB/2773A package.
3. The Package Design Safety Report (PDSR) [23] and the Packing and Handling Instructions for Elekta sources [24] have been updated to cover the updated special form capsule design and submitted to ONR as part of the modification application.
4. No specialist discipline input was necessary for this project due to the nature of the modification and the minor differences in the design of an updated certified special form capsule relative to the extant approval.
5. ONR’s assessment of the extension request was therefore focused on review of:

* the updated special form capsule design;
* any outstanding issues from the previous renewal; and
* operational experience and relevant transport incidents since the last renewal.

## Details of Special Form Capsule

1. The SAFSHIELD GB/2773A package design is utilised by Elekta and CNL for the transport of Co-60 sources used in gamma knife sets for cancer treatments. These sources comprise sealed sources of special form and non-special form materials.
2. Elekta has previously obtained special form capsules from Nordion, as specified in the extant CoA. It has now contracted Studsvik Nuclear AB (SNAB) as an alternative supplier of Co-60 sources. There are minor differences in the dimensions and design of the updated special form capsule design produced by SNAB as detailed in [2], which has been certified as special form by the Swedish CA in [25].
3. The compound bushing design is unchanged, however an additional engineering drawing has been produced for the compound bushing assembly containing SNAB sources.
4. I judge that the design differences between the Nordion and SNAB special form capsule designs are trivial and that no specialist assessment is required, as per the agreed permissioning strategy [22].

## Review of Previous Renewal

1. At the last full renewal of the GB/2773A package design approval, the human factors assessment identified some shortcomings with respect to recognised good practice in operating and handling instructions. As a result, the CoA was limited to 1 year to allow the applicant to address the issues raised by ONR. The applicant completed a programme of work to improve these instructions to ONR’s satisfaction and the CoA was extended for a further 4 years, i.e. to provide a full 5 year period until the next renewal.
2. I have reviewed the Project Assessment Report (PAR) from the 2020 renewal and the later decision record [26, 27] and there are no identified issues that remain outstanding. In addition, there have been no relevant changes in the requirements of IAEA SSR-6 (as reflected in the relevant modal regulations, as enacted in UK law) that require consideration.
3. The PDSR for the SAFSHIELD GB/2773A package design [23] states that shipments by CNL may include a special form capsule manufactured by International Isotopes Inc. that is certified by the United States CA in [28]. This was not specified on the extant CoA. The drawing reference for this special form capsule will be included for completeness on the revised CoA.

## Review of Operational Experience & Relevant Transport Incidents

1. I have confirmed with the applicant that there have been no operational issues or transport incidents involving the SAFSHIELD GB/2773A package design or similar packages since the last renewal [29].

# Matters Arising from ONRs Work

1. There are no matters arising from ONR’s assessment of this modification application.

# Conclusions

1. Based on the work carried out by ONR, I conclude that the SAFSHIELD GB/2773A/B(U) package design continues to meet the requirements of the relevant modal regulations as enacted in UK law.

# Recommendations

1. I recommend that:

* ONR grants approval of Modification CN073 to the SAFSHIELD package design GB/2773A/B(U) for transport by road, rail, sea and air;
* that certificate of approval is updated as GB/2773A/B(U) (Rev.10) to include details of the updated SNAB special form capsule design for Elekta; and
* that certificate of approval is also updated as GB/2773A/B(U) (Rev.10) to include details of the International Isotopes Inc special form capsule design for CNL.

# References

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| [1] | Email from Croft Associates Ltd to ONR, "GB/2773A/B(U)-96 Rev 9 Change Notification (Category B)", April 2023, WIReD Ref: ONRW-2019369590-2387. |
| [2] | "Competent Authority Change Notification: Update to 2773A Elekta Special Form Capsule", Modification CN073 Issue A, April 2023, WIReD Ref: ONRW-2019369590-2384. |
| [3] | "Certificate of Approval of Package Design for the Carriage of Radioactive Material", GB/2773A/B(U)-96 (Rev 9), CM9 Ref: 2021/29577. |
| [4] | The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (CDG) 2009, (SI 2009 No. 1348). www.legislation.gov.uk. |
| [5] | The Energy Act 2013, Chapter 32. |
| [6] | Agency Agreements, Memoranda of Understanding (MoUs) and Working Arrangements Protocol - http://www.onr.org.uk/agency-agreements-mou.htm. |
| [7] | Agreement with Department of Agriculture Environment & Rural Affairs (DAERA) (Northern Ireland) - http://www.onr.org.uk/documents/2014/transport-aa-northern-ireland.pdf. |
| [8] | Agreement with Secretary of State for Transport (including the MCA) - http://www.onr.org.uk/documents/2014/mca-aa.pdf. |
| [9] | Agreement with the Civil Aviation Authority - http://www.onr.org.uk/documents/2014/caa-aa.pdf. |
| [10] | The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (Northern Ireland) 2010, (SR 2010 No 160). www.legislation.gov.uk. |
| [11] | United Nations Economic Commission for Europe (UNECE), Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) 2023 Edition, www.unece.org. |
| [12] | Intergovernmental Organisation for International Carriage by Rail (OTIF), Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) 2023 Edition, www.otif.org. |
| [13] | International Maritime Dangerous Goods (IMDG) Code 2020 Edition incorporating Amendment 40-20. |
| [14] | The Merchant Shipping Act 1995 (1995 c. 21). www.legislation.gov.uk. |
| [15] | The Merchant Shipping (Dangerous Goods and Marine Pollutants) Regulations 1997 (SI 1997 No. 2367). www.legislation.gov.uk. |
| [16] | International Civil Aviation Organisation’s Technical Instructions for the Safe Transport of Dangerous Goods by Air, ICAO TI, 2019-2020 Edition. |
| [17] | The Air Navigation Order 2016 (SI 2016 No. 765). www.legislation.gov.uk. |
| [18] | The Air Navigation (Dangerous Goods) Regulations 2002 (SI 2002 No.2786). www.legislation.gov.uk. |
| [19] | IAEA Safety Standards for Protecting People and the Environment, Specific Safety Requirements No. SSR-6, ‘Regulations for the Safe Transport of Radioactive Material’, 2018 Edition. www.iaea.org. |
| [20] | IAEA Safety Standards for Protecting People and the Environment, Specific Safety Guide No. SSG-26 (Rev. 1), "Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material (2018 Edition)". |
| [21] | TRA-PER-GD-001 Revision 3, "Transport Permissioning Assessment". |
| [22] | WIReD Permissioning Record PR-01250. |
| [23] | DSR GB/2773A/B(U)-96, "Design Safety Report for Package Design No 2773A", Issue Q, February 2023, WIReD Ref: ONRW-2019369590-2386. |
| [24] | CPI 006, "Packing and Handling Instructions for Package Design No GB/2773A Elekta Contents", Issue X, February 2023, WIReD Ref: ONRW-2019369590-2385. |
| [25] | SSM2022-5773-7, "Swedish Radiation Safety Authority - Certificate of Approval for Design of Special Form Radioactive Material", October 2022. |
| [26] | ONR-TD-PAR-20-001, "Assessment of Approval for Renewal of the GB/2773A Package Design", June 2020, CM9 Ref: 2020/181780. |
| [27] | ONR-TD-DR-21-004, "Transport Permisisoning - Decision Record: Design Safety Report for Package Design No. 2773A", April 2021, CM9 Ref: 2021/29475. |
| [28] | USA/0707/S-96 Revision 6, "IAEA Certificate of Competent Authority Special Form Radioactive Materials", December 2019, WIReD Ref: ONRW-2019369590-3503. |
| [29] | ONR-TD-CR-23-105, "Croft Associates - Initial Meeting for GB/2773A Modification Application", June 2023, CM9 Ref: 2023/34740. |

1. *Known as modal regulations as they apply to a specific mode of transport, e.g. road, rail, sea and air* [↑](#footnote-ref-2)