



**Delicensing of the GEHC Cardiff Nuclear Licensed Site**  
**Assessment of licensee's delicensing application**

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## EXECUTIVE SUMMARY

### Delicensing of the Cardiff Nuclear Licensed Site

#### Permission Requested]

The licensee, GE Healthcare Limited (GEHC) has requested in a letter to the Office for Nuclear Regulation (ONR) dated 26<sup>th</sup> September 2019 that the nuclear site licence (38C) for the Cardiff Nuclear Licensed Site (CNLS) within the Maynard Centre is revoked, and that the period of responsibility under that licence is ended (this process is known as ‘delicensing’).

In support of its request the licensee has submitted an application pack (delicensing safety case) to ONR as evidence in support of its claim to have met the requirement of section 5(3) of the Nuclear Installations Act 1965 that in its opinion there has ceased to be any danger from ionising radiations from anything on the licensed site.

#### Background

The licensee, GEHC, owns and operates two licensed sites under the Nuclear Installations Act 1965: one in England in Amersham, Buckinghamshire (the Grove Centre); and the CNLS. GEHC has operated these licensed sites since its acquisition of Amersham plc in April 2004.

Until April 2010 the Maynard Centre manufactured radio-chemicals for the healthcare and life sciences research markets. The principal radionuclides used, in terms of radioactivity throughputs and inventories, were tritium and carbon-14, originally produced in nuclear reactors located elsewhere. Radiochemical manufacturing ceased at the Maynard Centre in 2010.

In April 2015 ONR revoked site licence 38B as it agreed that GEHC had met the “no danger criterion” for the majority of the Maynard Centre following an extensive decommissioning, remediation and sampling & assessment project. In parallel with the revocation ONR issued a replacement site licence to GEHC for the bulk storage of matter on what remained of the original licensed site, (Site Licence No. 38C). The reduced licensed site, known as the Cardiff Nuclear Licensed Site (CNLS), consisted of an Intermediate Level Waste (ILW) store and a number of small ancillary buildings including two other waste stores. The site has also housed an effluent treatment plant, known as the Liquid Handling Centre, which had been decommissioned and removed prior to the replacement site licence being issued.

The ILW store contained two waste types: miscellaneous wastes containing or contaminated by either tritium or carbon 14.

In 2016 GEHC implemented a project to remove all waste from the CNLS and to carry out a programme of work to demonstrate that the site was suitable to be delicensed.

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

ONR has carried out radiological protection assessment of GEHC’s delicensing safety case to support the application for delicensing of the CNLS. The safety case was examined and assessed by ONR and in accordance with ONR’s internal procedures, ONR commissioned independent radiological monitoring, sampling, assessment and analysis by the Public Health England. This assisted ONR’s assessment in making a judgement as to the suitability and adequacy of the licensee’s request.

ONR also assessed the licensee’s arrangements for the ongoing storage of documents as required by ONR’s published guidance on delicensing existing licensed nuclear sites. The arrangements were deemed to be adequate.

### **Matters arising from ONR's work**

All issues identified during ONR's de-licensing assessment and inspection work that needed to be addressed prior to the revocation of the site licence have been resolved.

### **Conclusions**

From the assessment of the licensee's delicensing safety case and the independent verification carried out by PHE, ONR considers that there is "no danger" from ionising radiation from what remains of the Cardiff licensed site.

Therefore the licensee's period of responsibility under NIA 65 may be ended.

### **Recommendation**

On the basis of the application submitted by GEHC and the conclusions set out above it is recommended that:-

- ONR's Decommissioning Fuel & Waste Sites Superintending Inspector accepts this Project Assessment Report to confirm support for the ONR technical and regulatory arguments that justify the revocation of the nuclear site licence for the Cardiff nuclear licensed site.
- ONR's Chief Nuclear Inspector revokes nuclear site licence number 38C for the Cardiff nuclear licensed site thereby giving effect to ONR's opinion that there has ceased to be any danger from ionising radiations from anything remaining on the site.

## LIST OF ABBREVIATIONS

ALARP	As low as reasonably practicable
CNSS	Civil Nuclear Security & Safeguards (ONR)
CNLS	Cardiff nuclear licensed site
GEHC	GE Healthcare Limited
HOW2	(Office for Nuclear Regulation) Business Management System
HSE	Health and Safety Executive
ILW	Intermediate Level Waste
NIA65	Nuclear Installations Act 1965
NSL	Nuclear site licence
ONR	Office for Nuclear Regulation
PHE	Public Health England
RP	Radiological Protection

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## 1 PERMISSION REQUESTED

1. The licensee, GE Healthcare Limited (GEHC) has requested in a letter to the Office for Nuclear Regulation (ONR) dated 26 September 2019 (Ref 1) that the nuclear site licence (No. 38C) for its licensed site in Cardiff (within the Maynard Centre) is revoked, and that the period of responsibility under that licence is ended.
2. The Licensee has submitted an application pack (delicensing safety case) to ONR as evidence in support of its claim, that in its opinion, there has ceased to be any danger from ionising radiations from anything on the site or, as the case may be, on the part of it in question.
3. Section 5(1)(a) of the Nuclear Installations Act 1965 (NIA65)(Ref. 2), empowers the appropriate national authority (in this case ONR) to revoke a nuclear site license. For this to occur ONR informs the Licensee that their 'period of responsibility' for the nuclear licensed site is coming to an end (Section 5(14)(b)) on a certain date, only when ONR gives its opinion to the Licensee that there has ceased to be any danger from ionising radiation from the site (Section 5(15)(a)). This is known as delicensing.
4. When considering an application to delicense all or part of a licensed site, the policy statement on delicensing, "HSE Criterion for Delicensing Nuclear Sites", (Ref. 8) specifies the requirements for enabling "no danger" under NIA65, of which the main requirements are:
  - 'A demonstration that any residual radioactivity above background radioactivity, which remains on the site, which may or may not have arisen from licensable activities, will lead to a risk of death to an individual using the site for any reasonably foreseeable purpose, of no greater than 1 in a million per year'.
  - 'a dose to an individual of 10  $\mu$ Sv or less per year broadly equates to the 1 in a million per year 'no danger' criterion and is consistent with other legislation and international advice relating to the radiological protection of the public'.
  - 'If an operator can demonstrate that the [ONR] criterion can be met, [ONR] may be content for the site to be removed from the requirements of the NIA65. However, the overarching requirements of the Health and Safety at Work Act, 1974, which requires operators to ensure "health and safety" so far as is reasonably practicable (or, equivalently, that risks are reduced "As Low As Reasonably Practicable" – ALARP) also apply and [ONR] will expect the operator to demonstrate that he has also considered these overarching ALARP requirements'.

Note: Much of the guidance and documentation relating to delicensing was prepared when ONR's predecessor organisations were part of the Health and Safety Executive (HSE) prior to ONR becoming an independent body; hence many of the references refer to HSE procedures which are now applied to GB nuclear sites by ONR. Where responsibility has transferred to ONR from HSE this is denoted in the text as [ONR].

## 2 BACKGROUND

5. The licensee, GEHC, owns and operates two nuclear licensed sites under the NIA65: one in England in Amersham, Buckinghamshire (the Grove Centre); and the other in Wales in Cardiff (within the Maynard Centre). GEHC has operated these licensed sites since its acquisition of Amersham plc in April 2004 and possesses a full set of licence condition compliance arrangements for the sites including a Nuclear Safety Committee.
6. Until April 2010 the Maynard Centre manufactured radio-chemicals for the healthcare and life sciences research markets. The principal radionuclides used, in terms of

radioactivity throughputs and inventories, were tritium and carbon-14, originally produced in nuclear reactors located elsewhere.

7. The radioactive waste produced as a result of radiochemical manufacturing was placed into packages and transported to the waste handling complex on the site where it was either placed into drums for storage or processed for disposal off site depending on the radioactive content of the waste. Radiochemical manufacturing ceased at the Maynard Centre in 2010.
8. In April 2015 ONR agreed to revoke site licence 38B as it agreed that GEHC had met the “no danger criterion” for the majority of the Maynard Centre following an extensive decommissioning, remediation and sampling & assessment project, known as Project Oak. In parallel with the revocation ONR issued a replacement site licence to GEHC for the bulk storage of matter on what remained of the original licensed site, nuclear site licence 38C. The new, smaller, licensed site, known as Cardiff Nuclear Licensed Site (CNLS), consisted of an Intermediate Level Waste (ILW) store and a number of small ancillary buildings including two other waste stores. The site has also housed an effluent treatment plant, known as the Liquid Handling Centre, which had been decommissioned and removed prior to the replacement site licence being issued.
9. GEHC produced a revised site map (Ref 3) when the site was re-licensed in 2015, which showed the whole of the Cardiff site, sub-divided into the area to be de-licensed and the area to be covered by the replacement nuclear site licence (NSL 38C). The area to be de-licensed is the whole of the area covered by NSL 38C, there will be no remaining licensed land on the Cardiff site, following this de-licensing exercise.
10. The ILW store, known as the Materials Handling Centre (MHC), contained two waste types: miscellaneous wastes containing or contaminated by either tritium or carbon 14.
11. In 2016 GEHC implemented a project, known as ‘Project Clear’, to remove all waste from the CNLS and to carry out a programme of work to demonstrate that the site met the “no danger criterion” and was therefore suitable to be delicensed.
12. The objective of this Project Assessment Report (PAR) is to describe the assessment carried out by ONR of the licensee’s application and make recommendations as appropriate regarding delicensing of the CNLS.

### **3 ASSESSMENT AND INSPECTION WORK CARRIED OUT BY ONR IN CONSIDERATION OF THIS REQUEST**

13. Section 3 of this project assessment report describes the assessment and inspection work carried out by ONR. ONR’s conclusions are described in section 5 below.

#### **3.1 RADIOLOGICAL PROTECTION ASSESSMENT IN SUPPORT OF DELICENSING**

14. The licensee’s application pack (delicensing safety case) has been assessed by ONR’s Radiological Protection (RP) specialism and an Assessment Report has been produced (Ref 4). The assessment was undertaken in accordance with the requirements of the ONR Guide NS-PER-GD-014 (Ref 5). The ONR Safety Assessment Principles (SAPs) (Ref. 6), together with supporting Technical Assessment Guides (TAG) (Ref. 7), were used as the basis for the assessment.
15. The objective of the assessment was to judge the licensee’s claim that any residual radioactivity above background radioactivity, which remains on the site, which may or may not have arisen from licensable activities, will lead to a risk of death to an individual using the site for any reasonably foreseeable purpose, of no greater than 1 in a million per year i.e. the requirement of the “no danger” criterion had been met.



The assessment was carried out in accordance with the ONR Guidance to inspectors on the interpretation and implementation of the criterion of no danger for the delicensing of nuclear sites, August 2008, <http://www.onr.org.uk/delicenceguide.pdf> (Ref 9).

16. In accordance with the ONR guidance Public Health England (PHE) was commissioned to undertake independent radiological measurements (monitoring, sampling, and analysis) and assessment of the delicensing safety case submitted by GEHC. The PHE assessment and findings has been written up in a report (Ref.10) provided to ONR.
17. Following the review of information provided by GEHC and taking into account the assessment undertaken by PHE, the findings of the ONR RP assessment are that the GEHC delicensing safety case is adequate and provides appropriate evidence to corroborate the claim that the CNLS has met the deregulation criteria and as such 'no danger' from ionising radiation. The conclusion of the RP assessment is described in paragraph 5 below.

### **3.2 SECURITY MATTERS**

18. Following a series of meetings between ONR Nuclear Safety and ONR Civil Nuclear Security & Safeguards (CNSS) a Decision Record (Ref 11) was produced by ONR CNSS concluding that the GEHC Security Plan will be revoked at the same time as the site licence.

### **3.3 RETENTION OF RECORDS**

19. The ONR guide on the Delicensing Process for Existing Licensed Nuclear Sites (Ref 12) requires that "Any person who may have suffered harm as a consequence of activities on a licensed nuclear site is entitled to make a claim for compensation for up to 30 years after the date of the occurrence which gave rise to the claim (section 15 of NIA65). Consequently, upon delicensing and/or the ending of the period of responsibility for all or part of a licensed site, the licensee must make secure arrangements for relevant records to be retained for at least that period."
20. The licensee has made arrangements, which appear to be adequate, to satisfy this requirement for document retention. These arrangements are described in the licensee's document "Safety and Environmental Deregulation Case for the CNLS (Ref 13).

### **3.4 CONSULTATION**

21. ONR is required by NIA65 to consult with the appropriate environment authority before revoking a NSL. Natural Resources Wales has been consulted and it has confirmed that it does not believe there is any legal prejudice between the revocation of a site licence and the process it is carrying out under the Environmental Permitting Regulations 2016.
22. Nuclear regulation is not a devolved matter. ONR is not required to consult with the Welsh Government before revoking the nuclear site licence for a Welsh site. However the Welsh Minister for Natural Resources has been notified of the licensee's application and she has requested that the Welsh Government be informed of the outcome of ONR's assessment.

### **3.5 LEGAL RAMIFICATIONS OF DE-LICENSING**

23. NIA65 section 5 gives ONR the power to revoke a Nuclear Site Licence, but also states that the licensee's period of responsibility under the Act does not end until ONR gives notice in writing that there has ceased to be any danger from ionising radiations from anything remaining on the site. A revocation document, made under section 5 of the Act, has been drafted stating that the licensee's period of responsibility will end with the revocation of nuclear site licence 38C. The draft revocation has been reviewed by the Government Legal Department (Ref 14).

#### **4 MATTERS ARISING FROM ONR'S WORK**

24. None.

#### **5 CONCLUSIONS**

25. From the assessment of the licensee's delicensing safety case and the independent verification carried out by PHE, ONR considers that there is "no danger" from ionising radiation from what remains of the Cardiff nuclear licensed site.
26. Therefore the licensee's period of responsibility under NIA65 may be ended.

#### **6 RECOMMENDATIONS**

27. On the basis of the application submitted by GEHC and the conclusions set out in section 5 above it is recommended that:-
- ONR's Decommissioning Fuel & Waste Sites' Superintending Inspector accepts this Project Assessment Report to confirm support for the ONR technical and regulatory arguments that justify the revocation of the nuclear site licence for the Cardiff nuclear licensed site.
  - ONR's Chief Nuclear Inspector revokes nuclear site licence number 38C for the Cardiff nuclear licensed site thereby giving effect to ONR's opinion that there has ceased to be any danger from ionising radiations from anything remaining on the site.

## 7 REFERENCES

1. Letter from GEHC to ONR requesting revocation of nuclear site licence 38C for the Cardiff Nuclear Licensed site. CM9 ref 2019/332610
2. Nuclear Installations Act 1965 (as amended),  
<http://www.legislation.gov.uk/ukpga/1965/57>
3. Site Map CM9 ref 2015/156725
4. Radiological Protection Assessment in Support of Delicensing GE Healthcare Ltd Cardiff Nuclear Licensed Site. CM9 ref 2019/329140
5. *ONR HOW2 Guide - Purpose and Scope of Permissioning - NS-PER-GD-014 Revision 6* November 2019. <http://www.onr.org.uk/operational/assessment/index.htm>
6. *Safety Assessment Principles for Nuclear Facilities*. 2014 Edition Revision 0. November 2014. <http://www.onr.org.uk/saps/saps2014.pdf>.
7. Technical Assessment Guides – list under one reference, give hyperlink to top level table on web-site only, e.g.  
  
Fundamental principles, NS-TAST-GD-004 Revision 7, ONR, April 2019.  
Guidance on the Demonstration of ALARP (As Low As Reasonably Practicable), NS-TAST-GD-005 Revision 9, ONR, May 2018.  
Radiological Protection, NS-TAST-GD-038 Revision 8, ONR, November 2017.  
[http://www.onr.org.uk/operational/tech\\_asst\\_guides/index.htm](http://www.onr.org.uk/operational/tech_asst_guides/index.htm)
8. HSE Criterion for Delicensing Nuclear Sites, <http://www.onr.org.uk/delicensing.pdf>
9. Guidance to inspectors on the interpretation and implementation of the HSE policy criterion of no danger for the delicensing of nuclear sites, August 2008,  
<http://www.onr.org.uk/delicenceguide.pdf>
10. Assessment of documentation and measurements submitted in support of the delicensing of GE Healthcare, the Maynard Centre, Whitchurch, Cardiff, Wales, Public Health England, CRCE-DSD-008-2019, November 2019, 2019/345636.
11. ONR CNS Decision Record - To set a precedent for consistent and proportionate safety and security regulation through delicensing. CM9 ref 2019/10230
12. ONR Guide “The Delicensing Process for Existing Licensed Nuclear Sites” NS-PER-IN-005 Revision 2 CM9 ref 2016/259571
13. Safety and Environmental Deregulation case for the Cardiff Nuclear Licensed site (CNLS) CM9 ref 2019/332631
14. Government Legal department review of revocation CM9 ref 2019/348566