GE Healthcare The Maynard Centre Decommissioning Project

May 2010





Who are we?

GE Healthcare was formed following the purchase of the Amersham business and the merger with GE Medical Services division

GEHC has three nuclear licensed sites located in the UK:

- -Amersham
- -Harwell
- -Cardiff

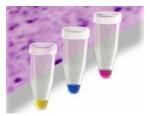


The Maynard Centre, Cardiff, Wales

Overview

- •c420 staff QA, Lean Six Sigma, Manufacturing, Development, Marketing, Engineering, EHS, Purchasing and Warehouse.
- •Principal reagent and kit manufacturing site for GEHC consumables business.







The Maynard Centre

The facility was built on a 30 acre green field site, which was manufacturing C14/H3 labelled products from 1980, up until cessation in late 2009 (H3) and April 2010 (C14)







End of an era

Business decision taken in Dec 2008 to:

- •Exit the Radiochemical/Custom Synthesis
- •Decommission and Delicense over 90% of site
- •Redefine the nuclear site boundary
- •Use de-licensed areas for growth opportunities





Project Aims

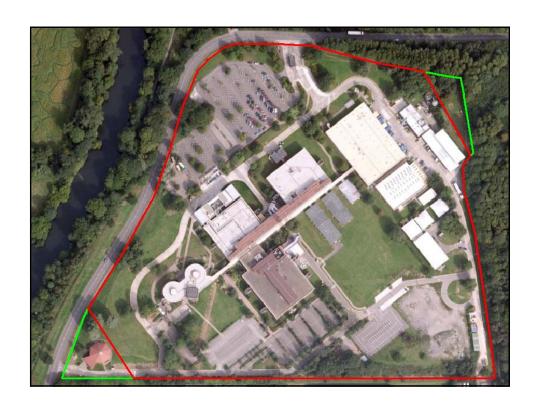
Following business closure a Decom Project Team was formed in Jan 2009 to

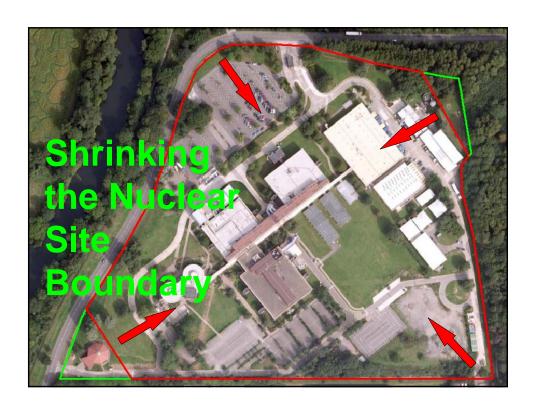
- Clear potential liabilities from around 90% of site
- Satisfy all regulatory requirements













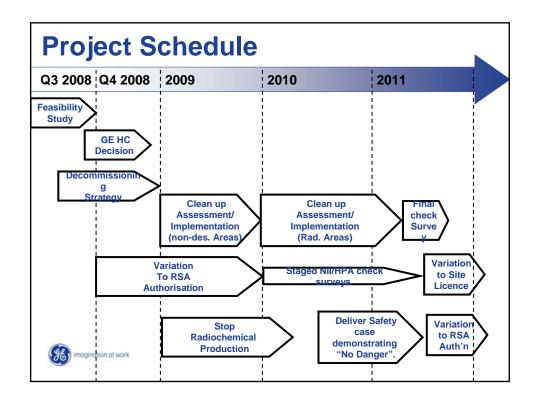
Project Deliverables

Building the foundations for future growth by:

- Clearing buildings for reuse by inactive processes
- Removing the main area of site from the NLS requirements







Regulatory position

The Maynard Centre is subject to two principal regulations as a result of its work with radioactivity:

- ☐ The Nuclear Installations Act administered by the NII which regulates the operation of the site.
- ☐ The Radioactive Substances Act administered by the EA which regulates radioactive wastes.

A site (or part of site) may be de-licensed from NIA if the operator demonstrates that 'no danger' from radioactivity remains on the site.

No Danger agreed as per RS.G.1.7 values:

H-3 100 Bq/g C-14 1 Bq/g



Delicencing Safety Case

The following criteria have been agreed with NII:

- Areas of site to be delicenced will be clearly identified;
- Activities for which licencing is required will no longer be carried out on that site;
- Risk factors from the remaining licenced site will be assessed, controlled and justified
- 'No danger' (i.e. no significant risk) will remain to any person from residual activity above background.
- The application for delicencing will be supported by a safety case that as a minimum will include demonstration of 'no danger' and ALARP.





DQO Application at TMC

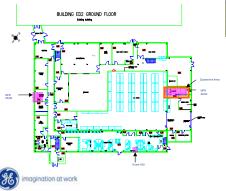
- GEHC has chosen to use the Data Quality Objectives methodology and support tools
- This approach relies on the use of statistical techniques to support clearance decisions and will underpin our site licence variation submission
- Analysis and DQO workshops completed for the first few buildings
- Clearance in Principle for the first building agreed with the NII in Jan 2010





Understand the History

- Staff knowledge
- Site Drawings
- Accident reports
- Project Files





- Identify Areas of heightened interest based upon operating history and unusual events
- Identify areas of common potential exposure



Using the history

History File developed and used in support of DQO application.

The building has never contained any radiologically designated areas (i.e. Controlled or Supervised) and has therefore always been a low radiological risk.

Very few instances of contamination above background have been identified.

Detailed history of unusual events constructed from operational records and staff interviews



Defining the decisions

Decision Statements:

- 1. The material will be analysed and if no contamination is found it will be declared as 'free from regulatory concern' with no additional control imposed on its disposal.
- 2. If radioactivity is found below 0.4 Bq/g added artificial radioactivity then the material will be exempt from the SOLA Exemption Orders ("The Radioactive Substances (Substances of Low Activity) Exemption Order 1986" and "The Radioactive Substances (Substances of Low Activity) Exemption (Amendment) Order 1992"). Restrictions may still be imposed on its subsequent disposal.
- 3. If remaining structures are found to be above the delicensing criteria then remedial actions will be required to remove identified areas of contamination.



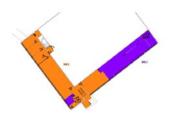


Defining the sampling zones

Conceptual Site Model developed and building zoned upon basis of previous history, similarity of operations and areas of particular interest which were:

- The Central Laboratory located on the first floor
- The personal decontamination room located on the first floor
- The Quarantine area located within the Stores area on the ground floor.







Preparing sampling plans

Zones were sub-divided into material matrices (e.g. carpet, plasterboard etc) and number of respective samples required identified.

The equation used to calculate the number of samples is based on a Sign test. For this site, the null hypothesis is rejected in favour of the alternative one if the mean is sufficiently smaller than the threshold. The number of samples will be increased by at least 20% to account for missing or unusable data and uncertainty in the calculated value of sample numbers.

A nonparametric systematic grid sampling approach was selected to determine the number of samples. A nonparametric formula was chosen because the conceptual model and historical information (e.g., historical data from this site or a very similar site) indicate that typical parametric assumptions may not be true.

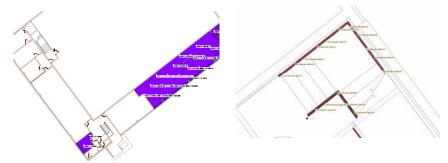
Locating the sample points over a systematic grid with a random start ensures spatial coverage of the site







Sample Analysis Plans for each zone identify location and reference number for each sample. Shown diagrammatically using VSP tool.



Total Number of samples for ED2: 626 which were analysed for both ^{3}H and ^{14}C .



Locating the sampling points

Sample Analysis Plans for each zone identify location and reference number for each sample. Shown diagrammatically using VSP tool.





ED2 Clearance in Principle

Majority of residual building structure satisfies internal delicencing criteria, further consideration of remedial action for 3 areas;

- Concrete under previous location of Cold room
- ➤ Material in gutters
- Paint on internal metalwork structures.





Clearance in Principle report

- Executive Summary
- Outline of building history and previous events.
- Summary of DQO process and development of Sample Analysis plans
- Summary of DQA process and discussion of results and conclusions
- Outline of remediation plans and further sample analysis to ensure that 'no danger' criteria can be satisfied
- Overall ALARP argument for remaining materials within the building
- Identification of control mechanisms to prevent any further cross contamination of the building.



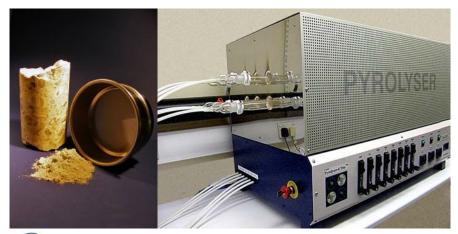


DQO Summary

- Robust and rigorous process supported by fully validated statistical calculations
- Provides a clear and consistent basis to prepare the clearance submission
- Accepted and agreed by the EA, NII and HPA
- Underpinned by a solid and high integrity sampling & analysis procedures



Sampling & Analysis





Collect the Samples and

- •Analysems collect samples.
- Chain of custody to laboratory.
- Sample storage and preservation important





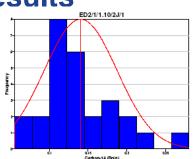




- Laboratory uses best techniques to determine 3H and 14 C levels in samples.
- Majority of analysis done in-house

Understand the Results

Statistical tests applied to evaluate data.



Zone 8	Delicensing		
	Individual Tritium	Individual Carbon-14	Combined Waste ¹⁴ C + ³ H
Specified number of samples to be collected	14	14	
Number of sample results, n	14	14	
Minimum value, Min (Bq/g)	1.30	0.32	
Maximum value, Max (Bq/g)	5.20	1.90	
Mean (Bq/g)	2.59	0.88	
Standard Deviation (Bq/g)	1.30	0.47	
Result of Shapiro-Wilk Test Statistic at 5% significance level	Maybe normal	Non-normal	
95% Parametric UCL (Bq/g)	3.21	0.66	
95% Non-Parametric UCL (Bq/g)	4.10	0.34	
Chosen 95% UCL resulting from normality test (Bq/g)	3.21	0.34	0.66
MARSSIM Conclusion	Clean	Clean	



imagination at work

Impact of DQO on Sampling

Initial delicensing sample numbers upper estimate was >100K*

Using DQO approach has reduced sample numbers to c10K*

Using typical sample costs (@£200/ea) potential reduction in costs from over £20M to £2M

*Excludes waste samples



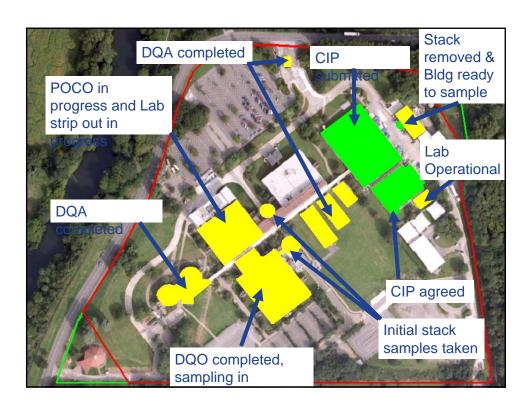


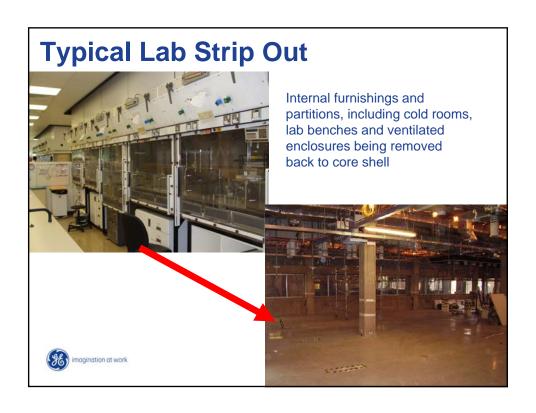
Project Status











Thank you



