



NDA–UKHSA Epidemiology Governance Group Annual Report FY2023/2024

EXECUTIVE SUMMARY

The Epidemiology Governance Group of the Nuclear Decommissioning Authority (NDA) and the UK Health Security Agency (UKHSA) exists to provide independent governance and oversight of epidemiology and radiobiology work undertaken using NDA-owned assets.

In line with agreed strategy, the assets of the NDA Epidemiology Programme were transferred to UKHSA ownership on 31 December 2023, and the NDA Epidemiology Programme concluded on 31 March 2024.

Following asset transfer, responsibility for the on-going governance of the assets passed to the NRRW Data Governance Group, and the few outstanding actions of the NDA–UKHSA EGG passed with them.

Further information on the epidemiology and radiobiology work can be found online at: www.gov.uk/government/collections/radiation-epidemiology

GOVERNANCE ACTIVITIES

The Epidemiology Governance Group of the Nuclear Decommissioning Authority (NDA) and the UK Health Security Agency (UKHSA) was established to provide independent governance and oversight of epidemiology and radiobiology work undertaken in relation to the ex-BNFL and ex-UKAEA radiation worker cohorts, ensuring that appropriate ethical approval was in place before granting use of the research assets.

The Governance Group membership included representatives of the NDA and UKHSA, data custodians, representatives of both the management and workforces with responsibility (or legacy responsibility) for members of the study cohorts, and an independent chair. The trade union representatives are from GMB, Prospect and UNITE.

This annual report contains a summary of the FY2023/2024 year's activity in relation to work governed by the NDA–UKHSA Epidemiology Governance Group.

The final meeting of the NDA–UKHSA Epidemiology Governance Group occurred on 8 March 2024, when the Group confirmed that the asset transfer to UKHSA had been completed appropriately. The NDA Epidemiology Programme was formally concluded on 31 March 2024.

MERGER WITH NATIONAL REGISTRY FOR RADIATION WORKERS

Following a review of various options for managing the ongoing research epidemiology and radiobiology research programme and associated assets, the NDA published a Preferred Option paper in 2015. The NDA concluded that the preferred option was to “further develop a strategic relationship with UKHSA with the long-term aim of restructuring the ownership and management of assets”, and this to be implemented by the transfer of ownership of NDA’s epidemiology assets to UKHSA where it would merge with the National Registry for Radiation Workers (NRRW) epidemiology research programme; effectively uniting all of UK plc’s radiation epidemiology research assets on one place.

Prior to the transfer of ownership and control of the ex-BNFL and ex-UKAEA studies to UKHSA, the opinion of an NHS Research Ethics Committee was sought to confirm that the merger was appropriate, and a ‘favourable opinion’ for the proposed merger was granted in May 2021. The approval lasts five years and must be renewed periodically.

As neither of the studies had been established on the basis of individual informed consent to process personal data, each of the studies held a Section 251 exemption under Regulation 3 or 5 of the Health Service (Control of Patient Information) Regulations 2002 to process personal data for public health benefit. A new application for a Section 251 exemption to support the ongoing processing of personal data on the same basis for the expanded study was made to the PHE Caldicott Guardian. Approval was granted in June 2021, and is reviewed and renewed annually.

A new NRRW Data Governance Group was set up to oversee the use of data for surveillance and research from the merged study. Modelled on the NDA-UKHSA Epidemiology Governance Group, this independently chaired group has representatives of UKHSA management, major employers whose workers are part of NRRW (including NDA group) and Trades Union representatives. There is also a lay member of the cohort to represent the interests of members not in trades unions. NRRW has a website upon which new research projects are announced, and the terms of reference and minutes of the meeting of the Governance Group are published (Radiation workers and their health: national study - GOV.UK (www.gov.uk)). At their July 2023 meeting, the NDA-UKHSA Governance Group formally confirmed that they were content that the new NRRW governance arrangements are suitable to maintain the future custodianship of the assets.

The required restructuring activities were completed on schedule in mid-December 2023, and legal transfer of the NDA Epidemiology Assets to UKHSA occurred on 31 December 2023.

RESEARCH PROJECTS

Research projects are undertaken to improve the understanding of the effects of radiation and with the aim of protecting the health of workers and the wider population. The Governance Group assures that research activity using the assets of the ex-BNFL and ex-UKAEA cohorts is consistent with good practice; the Governance Group does not directly commission or undertake research.

Given the restructuring of the ownership of assets, the decision was taken not to begin any new research projects until the transition was complete. The project below commenced prior to FY2022/23.

iPAUW: International Pooled Analysis of Uranium processing Workers

The Governance Group gave support to UKHSA's participation in an international research project led by the University of California, pooling and analysing data from sixteen cohorts of uranium processing workers from the USA, Canada, France, Germany, Russia and the UK. The study aims to increase understanding of the risks associated with exposure to long-lived uranium radionuclides, the predominant exposures of uranium processing workers such as those at the ex-BNFL Springfields site in the UK. To facilitate this, NDA had a Data Sharing Agreement (DSA) in place to share an anonymised dataset (a 9,378 person subset of the BNFL cohort) with the University of California.

Although the UK data had been ready to go since December 2022, it had not yet been sent due to delays from other participating organisations. In discussion with UKHSA, NDA decided that it was appropriate to wait to send the UK dataset until after Asset Transfer had taken place. As UKHSA will then be the Data Owner, this will mean that UKHSA needed to prepare a suitable DSA (the NDA-UoC DSA was terminated). NDA group's participation in the iPAUW study will still be acknowledged.

UKHSA statisticians will be involved in the analysis of the pooled data but also undertook a preliminary analysis of the Springfields cohort first to get a good understanding of what the UK component of the pooled study will bring to the analysis of the pooled data. A draft paper for publication was prepared in March 2024, and will be reviewed by the NRRW Data Governance Group prior to issue.

ASSETS

Permission to use the assets of the NDA Epidemiology Programme was granted by NDA after consultation with the Governance Group, who considered the risks and benefits of all research proposals received. All research proposals needed to have the appropriate Research Ethics Committee approvals in place prior to commencement. Only after approval of the EGG did NDA grant permission.

Following the legal transfer of the NDA epidemiology assets to UKHSA on 31 December 2023, permissioning of the use of the assets passed to the NRRW Data Governance Group.

Ex-BNFL and ex-UKAEA Databases

The databases holding the information required for the ex-BNFL and the ex-UKAEA epidemiology projects were managed by on NDA's behalf by UKHSA.

To enable merger of the two NDA databases with UKHSA's NRRW database, work was undertaken to create a new database management system that was needed to manage the three incompatible databases together. Work to develop the new database system commenced in November 2019 and completed in November 2023.

Biological Samples

NDA's Biological Sample Archive (the 'BioArchive') is a collection of samples collected with consent from workers at Sellafield. The BioArchive has been stored UKHSA Culture Collections facility at Porton Down since February 2023, with the contract for storage managed on NDA's behalf by UKHSA.

STAKEHOLDERS AND RELATED ENGAGEMENTS

The Governance Group met three times during the reporting year, on 14 July 2023, 17 November 2023 and 8 March 2024.

UKHSA researchers have engaged throughout the year with other radiation researchers within the UK and internationally primarily at scientific meetings or conferences. The aim is to promote awareness of the cohort among the radiation protection community and also to develop links that will foster opportunities for collaborative research that will be more informative than studying the cohort on its own.

In August 2023, two researchers from UKHSA presented the results of our Molecular Epidemiology Pilot Study at the International Congress for Radiation Research in Montreal.

ANNUAL REQUIREMENTS

Terms of Reference

The terms of reference for the Governance Group were reviewed at its meeting held on 12 March 2021 and agreed as fit-for-purpose for the anticipated remaining three years of the Governance Group's existence. A copy of the terms of reference can be found at Appendix A.

Information Governance (IG) Training

All relevant staff have completed annual IG training.

Subject Access Requests

No subject access requests were received during the FY2023/2024 period.

Caldicott Audits

A Caldicott audit of the ex-UKAEA and ex-BNFL database work was last conducted in August 2023 and reported a satisfactory outcome.

Cohort Member Opt-Out Reminder

The NDA programme was a records-based project, which means that details for each individual are drawn from existing records and it did not require individuals to be contacted for data or to complete a questionnaire. This approach reduced the impact on the

individual, but it also reduced the risk of bias in the study due to the response of participants.

The NDA programme operated on an 'opt-out' policy by which any individual may request that their details are either not included in any study or not included in a particular study. Historically, the number of people choosing to take this option was very low. This ensured that the research findings, which are intended to inform both radiation workers themselves as well as the scientific and medical community, were more valid than if a significant number of workers opt-out. New studies are announced in a number of ways (such as a company newsletters and this annual report) to allow individuals to opt-out. The size and historical nature of the databases means that it is not practicable to contact participants individually when a new study is proposed. It is possible for participants to opt-out of the study by contacting the UKHSA Radiation Epidemiology Group by emailing radiationworkerepidemiology@ukhsa.gov.uk. This opt-out mechanism also applies to on-going participation following merger into the NRRW study.

The Trade Union representatives on the NDA-UKHSA governance group (and who now sit on the NRRW Data Governance Group) strongly encourage all workers to remain in the programmes which were set up to protect the health of all workers.

APPENDIX A – Terms of Reference

OFFICIAL

NDA-PHE Epidemiology Programme
Terms of Reference
Agreed 13 July 2018



NDA Radiation Epidemiology Programme



Public Health
England

NDA-PHE Epidemiology Governance Group

TERMS OF REFERENCE

A. Function

The NDA-PHE Epidemiology Governance Group (EGG) exists to provide independent governance and oversight of epidemiology and radiation biology work proposed or undertaken in relation to the ex-BNFL and ex-UKAEA radiation worker cohorts. This Governance Group will continue to have the power to veto any given research proposal or, in appropriate circumstances, to require the ceasing of any ongoing project.

B. Terms of Reference

- a) To assure that, as necessary, work associated with NDA radiation epidemiology worker databases has been subject to appropriate ethical review and approval;
- b) To decide on proposals for analysis taking into account advice (if available) from independent epidemiology and/or radiobiology experts as appropriate;
- c) To ensure that products of work undertaken under the NDA-PHE contract have been suitably reviewed;
- d) To ensure that key stakeholders, including study participants, are briefed prior to publication or other dissemination.
- e) To ensure that the programme of work is effectively communicated, for example by means of an annual report of work undertaken that is made accessible to study participants and to encourage publication of research findings.

C. Membership of the group

- a) Independent academic or medically qualified (but not necessarily still registered to practice) or senior scientist (Chair) (appointment reviewed at least biennially);
- b) PHE management and research representative(s);
- c) NDA management and research representative(s);
- d) Data custodian(s);
- e) Representatives of both the management and workforces (trades union representatives) with responsibility (or legacy responsibility) for members of the study cohorts;
- f) Independent epidemiology and/or radiobiology experts as required;
- g) PHE secretariat (CRCE's Radiation Effects Department).
- h) A quorum for the group is defined as at least one member from each of the following groups: data controller (NDA), data processor (PHE), workforces (unions) and management.

D. Review of Terms of Reference

An agenda item, to formally review the Terms of Reference, will be scheduled biennially until such time as the NDA-PHE Epidemiology Governance Group is content that less frequent review is appropriate.

Terms of Reference reviewed and accepted.