



NDA–UKHSA Epidemiology Governance Group

ANNUAL REPORT FY2022/2023

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 in relation to the ex-BNFL and ex-UKAEA radiation worker cohorts, ensuring that appropriate ethical approval is in place before granting use of the research assets.

The Governance Group membership includes 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 FY2022/2023 year's activity in relation to work governed by the NDA–UKHSA Epidemiology Governance Group.

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

Forward strategy

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. To enact this, the following work has been undertaken:



- **Research Ethics Committee Approval.** Although both the NDA Programme and NRRW had their own REC Approvals, it was necessary to gain approval from the REC for the 'new NRRW' as proposed post-merger. After submission of the application, REC Approval has been granted, along with Section 251 Approval (for processing of personally identifiable data without consent).
- **New Governance Arrangements.** Whilst the NDA Programme is governed by this Governance Group, UKHSA's NRRW did not have such comprehensive governance arrangements and was essentially self-governed by the UKHSA Researchers. To demonstrate better oversight, UKHSA agreed to the establishment of an NRRW Governance Group (NRRW-GG) based upon the model used by NDA, and the terms of reference for the NRRW-GG give membership of governance group to NDA, the Sellafield Ltd Chief Medical Officer, and the Trades Unions (Unite, GMB and Prospect), all of whom are well placed to look after the on-going interests of NDA Employees and ex-Employees. The NRRW-GG first met in July 2022, and subsequently in January 2023. After the next meeting of NRRW-GG (July 2023), the NDA Governance Group will be asked to formally confirm that they are content that the new NRRW governance arrangements are suitable to maintain the future custodianship of the assets.
- **Asset Transfer Legal Agreement.** Work is progressing with NDA and UKHSA legal teams to prepare the necessary legal agreement for the transfer of assets from NDA to UKHSA.

The completion of restructuring activities is currently scheduled to be achieved by December 2023, and at this point the NDA Epidemiology Programme will conclude.

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 and the reporting of research is consistent with good practice; the Governance Group does not directly commission or undertake research.

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

iPAUW: International Pooled Analysis of Uranium processing Workers

UKHSA is participating in an international pooled analysis of uranium workers led by the University of California, including cohorts 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. The expected timescale for the project is 4-5 years. A favourable ethical opinion on the study has been received from an NHS Research Ethics Committee and support has been given by the NDA-UKHSA Epidemiology Governance Group. Data from the BNFL cohort concerning workers employed at the Springfields site will form the UK component of the study. UKHSA statisticians will be involved in the analysis of the pooled data and will also undertake 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.

Molecular Epidemiology Pilot Study

A proof-of-concept molecular epidemiology study using the retained former Sellafield worker biological samples commenced in 2021. This pilot study aimed to bring to together epidemiological and radiobiological techniques to explore a number of issues in radiation protection that are very difficult to address using either field in isolation. The worker samples were assessed for a range of biomarkers known to be linked to radiation exposure and the results linked to cancer incidence and mortality data held in the BNFL epidemiological database. Cytogenetic and genetic analysis of the samples and database linkage was completed in March 2023 and a project report produced. The pilot study demonstrated that studies combining radiobiological sampling with epidemiological data could lead to more complete analysis of individual worker risk.

Assets

Ex-BNFL and ex-UKAEA Databases

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

To enable merger of the two NDA databases with UKHSA's NRRW database, work has been 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 it is anticipated this will be completed in September 2023.

Biological Samples

NDA's Biological Sample Archive (the 'BioArchive') is a collection of 5066 samples collected with consent from workers at Sellafield. The BioArchive was stored at Newcastle Bio Bank (NBB) since 2011, with contract for storage managed on NDA's behalf by UKHSA. Permission to use samples from the BioArchive is granted by NDA after consultation with the Governance Group, who consider the risks and benefits of all research proposals received. All research proposals must have the



appropriate Research Ethics Committee approvals in place prior to commencement. Only after approval of the EGG do NDA grant permission.

As the NDA strategy for its Radiation Epidemiology Programme is to transfer all assets, including the BioArchive, to UKHSA ownership, UKHSA indicated that they would intend to use their 'in-house' bio-bank post-transfer. For this reason, coupled with a modest annual cost saving, it was decided to relocate the storage of the BioArchive to the UKHSA Culture Collections facility at Porton Down at the end of the current storage contract with NBB. This decision was taken after consultation with and the agreement of the EGG, and the BioArchive was relocated in February 2023. There were no issues reported with the transport, and no evidence that any sample was damaged during the relocation.

Stakeholders and related engagements

The Governance Group met three times during the reporting year, on 15 July 2022, 4 November 2022 and 3 March 2023.

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.

Key fields of interest have been epidemiology, radiobiology and dosimetry.

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 FY2022/2023 period.



Caldicott Audits

A Caldicott audit of the ex-UKAEA and ex-BNFL database work was conducted in April 2022 and reported a satisfactory outcome.

Cohort Member Opt-Out Reminder

The NDA programme is a records-based project, which means that details for each individual are drawn from existing records and it does not require individuals to be contacted for data or to complete a questionnaire. This approach reduces the impact on the individual, but it also reduces the risk of bias in the study due to the response of participants.

The NDA programme operates 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. Of course, we do hope that the number of people choosing to take this option will continue to be very low. This will ensure that the research findings, which are intended to inform both radiation workers themselves as well as the scientific and medical community, will be 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 will also apply to on-going participation when merged into the NRRW study.

The Trade Union representatives on the NDA-UKHSA 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

NDA Radiation Epidemiology Programme

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.