Merger of the ex-BNFL and ex-UKAEA Radiation Epidemiology studies into National Registry for Radiation Workers

Two long-term epidemiological studies of radiation and other workers formerly employed by British Nuclear Fuels Ltd and the United Kingdom Atomic Energy Authority will to be merged into the National Registry for Radiation Workers (NRRW) from 1st January 2024.

At the same time as transfer of ownership of the studies, an historic archive of biological samples retained from studies of radiation workers at Sellafield that have taken place over a 25-year period up to 2010 have also been passed to the care of UKHSA by the Nuclear Decommissioning Authority (NDA). This archive is now stored in the UKHSA Culture Collections facility at Porton Down.

Background

The NRRW was set up in 1975 to enable the surveillance of the health of UK radiation workers and provide direct evidence to assess whether radiation protection regulations and guidelines provide an adequate level of protection for UK radiation workers and the public.

The study population, or cohort, was drawn from workers from a wide range of industrial employer organisations, with participation on a voluntary, 'opt-out' basis. All of the major radiation employers in the United Kingdom are involved, including the Ministry of Defence (MoD), the sites formerly managed by British Nuclear Fuels Ltd (BNFL) and the UK Atomic Energy Authority (UKAEA), the Atomic Weapons Establishment (AWE), and also the nuclear power generation sites of Magnox and EdF. NRRW is run by UK Health Security Agency (UKHSA) on behalf of the Department for Health and Social Care.

Completely separately to the NRRW study, in the 1980s BNFL and UKAEA each set up their own similar but independent epidemiological studies which were for many years managed by those organisations. Over the years, a number of scientific papers were published based on data from these studies, however as they contained fewer workers the results were less statistically powerful than those based on the NRRW. However, the BNFL and UKAEA studies do have the advantage that they recorded internal dose data which enabled more wide-ranging analyses to be undertaken.

British Nuclear Fuels Ltd (BNFL) study: This cohort consists of those employees of BNFL who were employed at the Capenhurst, Chapelcross, Sellafield and Springfields nuclear sites prior to 2003. It comprises records for ~65,000 workers of whom ~42,000 are radiation workers. No new workers have been added to the cohort since BNFL was wound up by the UK government in 2004 at which time responsibility for the study passed to the Nuclear Decommissioning Authority (NDA). The BNFL study also possesses an archive of ~5000 biological samples which were donated by Sellafield employees to enable research into radiobiological causal mechanisms to be undertaken.

United Kingdom Atomic Energy Authority (UKAEA) study: This cohort consists of workers employed by UKAEA and its successor organisations. In around 2010 ownership of this cohort passed from UKAEA to the NDA. It comprises over 100,000 workers of whom ~75,000 are radiation workers. New workers continued to be routinely added to the cohort until 2020.

Since 2012, both the BNFL and UKAEA studies have been managed by the UKHSA under contract to NDA. The operation of the two studies is overseen by an independently chaired Epidemiology Governance Group, whose membership includes representatives of NDA group management, Sellafield Occupational Health, and the Trades Unions. UKHSA also operated the AWE study under contract to the MoD.

Justification for the merger

Whilst UKHSA have operated the two NDA studies and the AWE study separately of NRRW, almost all the radiation workers in the BNFL, UKAEA and AWE studies are also members of the NRRW study. This change will allow the best use of the data to provide evidence about the health risks of occupational exposure to radiation. Therefore, it was proposed that ownership of the BNFL, UKAEA and AWE studies be transferred to UKHSA, and these studies be merged into the NRRW to create a single national resource to study radiation risks. Following stakeholder engagement, the decision to transfer NDA assets to UKHSA ownership was taken and NDA's strategy published.

Benefits of this merger

1) **Increased statistical power to provide evidence about the risks of radiation exposure:**

   - NRRW was set up originally only with the capability to provide evidence about the risks of external radiation exposure. However, there is now great interest in the international scientific community for gathering evidence about the possible effects of internal exposures. Each of the BNFL, UKAEA and AWE studies have data which contains bioassay measurements from which internal doses can be calculated. As a result of the merger, the expanded NRRW will have record of

approximately 30,000 workers who were monitored for internal exposure and for whom internal organ doses can be calculated from the bioassay data transferred from the BNFL, UKAEA and AWE cohorts.

- When the health of radiation workers is compared to the general public, they are almost always found to be healthier because they are preselected (via a pre-employment medical) to be healthy – this is known as the 'healthy worker effect'. A comparison of the radiation workers' health to that of non-radiation workers employed at the same site, and who often undergo the same enhanced level of health monitoring as the radiation workers, provides a better comparison group than the general population particularly for diseases where lifestyle factors such as smoking, alcohol consumption, obesity and hypertension that vary round the country are important factors. The non-radiation worker components of the BNFL, UKAEA and AWE cohort will provide an ideal comparison control group for the NRRW.

2) Reduced administrative burden:

- A cost saving in management of the cohorts – Data about a worker would only be entered onto the NRRW once and not to NRRW and at least one other of these databases. Plus, only need to maintain one set of IT Infrastructure.
- A reduction in time spent on information governance and ethical approval issues – As these would only need to be considered such issues for one study (NRRW) and not all four studies.
- Improved data security – The data about a workers will be held in only one database and not four separate databases.

Preparations and approvals for the merger

Prior to the transfer of ownership and control of the BNFL, UKAEA and AWE 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.

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. A new application for a Section 251 exemption to support the ongoing processing of personal data without informed consent in 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 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)).

The NRRW programme draws from existing records, and it does not require individuals to be contacted for data or to complete a questionnaire. NRRW operates an 'opt-out' policy, by which any individual may request that their details are either not included in the study or for a particular research project by emailing radiationworkerepidemiology@ukhsa.gov.uk. The Trades Union representatives on the Governance Group strongly encourage all workers to remain in the programme which was set up to protect the health of all workers.

The future

Over the past four decades, the BNFL and UKAEA radiation epidemiology studies have provided important evidence as to the effect upon the health of radiation workers. The results of these studies have been published in scientific journals and are well-regarded worldwide. Merger with NRRW will strengthen the UK's leading position in this field of research, and the merged study will be one of the world's most powerful research tools into radiation epidemiology.

NDA group look forward to continuing their close relationship with UKHSA and will continue to support future radiation epidemiological research activities in support of NDA's mission.