

Medical Radionuclide Innovation Programme

Application Guidance



© Crown copyright 2023

This publication is licensed under the terms of the Open Government Licence v3.0 except where otherwise stated. To view this licence, visit <u>nationalarchives.gov.uk/doc/open-government-licence/version/3</u> or write to the Information Policy Team, The National Archives, Kew, London TW9 4DU, or email: <u>psi@nationalarchives.gsi.gov.uk</u>.

Where we have identified any third-party copyright information you will need to obtain permission from the copyright holders concerned.

Any enquiries regarding this publication should be sent to us at: <u>MRIP@beis.gov.uk</u>

Contents

Introduction	5
Background	
MRIP Innovation Project Workstream	6
Objectives	7
Alignment with other HMG programmes	
Application and Assessment Process	8
Stage 1: Application window open and preparation window	9
Application Cost Liability	10
Requests for clarification	10
Documentation Required	10
Stage 2: Eligibility Checks	12
Applicants Eligibility	12
Application Eligibility	
Cost limits	15
Additionality	15
Finance	15
Terms and Conditions	15
Self-certification	15
Stage 3 and 4: Evaluation	
Technical Assessment (40%)	17
Deliverability & Project Controls Assessment (30%)	
Economic Assessment (30%)	
Stage 5: MRIP Portfolio Assessment	19
Stages 6: Final Decisions on Award	19
Embargo – decisions on award	19
Notification of applicants	19
Decision on successful applicants	19
Internal HMG assurance and approvals processes	
Grant award	20
Publication of successful projects	

Important information for applicants	21
Applications from Consortia	21
Subsidy control assessment	21
Public Sector Equalities Duty assessment	
Terms and conditions	25
Reserved rights	
Detailed information requirements by section	
Section A: Eligibility & Financial Information	28
Section B: Technical Assessment	29
Section C: Deliverability and Project Controls Assessment	30
Section D: Economic Assessment	31
Section E: Applicant Equalities Information	32
Section F: Declarations	33

Introduction

Background

- 1. Nuclear power has a critical role to play in our future low carbon energy mix, but the UK will continue to rely on nuclear materials for more than just electricity generation; they will also be required for medicine.
- 2. Nuclear medicine involves the use of radioactive materials (radionuclides) to observe body functions (diagnostics) or to target diseased cells (therapy). In the UK around 700,000 nuclear medicine procedures using radionuclides are performed each year¹ and the demand for nuclear medicine procedures is set to grow as our population both ages and increases.
- 3. Whilst there are other factors that affect access to nuclear medicine, the UK's access to radionuclides and their respective radiopharmaceuticals for diagnosis and treatment continues to be a priority for clinicians and researchers. The UK currently imports the majority of the radionuclides used in nuclear medicine procedures from countries with research reactors e.g., the Netherlands and Belgium. These imports include almost 100% of the radionuclides required for Single-Photon Emission Computed Tomography (SPECT) scans and molecular radiotherapies. Those research reactors are ageing, which increases the risk of unplanned outages, and replacement projects are delayed. This leaves the UK vulnerable to potential global shortages.
- 4. His Majesty's Government (HMG) recognises the importance of continued access to radionuclides for medicine and in December 2022 launched the up to £6 million Medical Radionuclide Innovation Programme (MRIP). The Programme will focus on encouraging innovation in technologies and techniques that could support access to radionuclides and increase national resilience against global shortages, as well as building an evidence base to inform future decisions on radionuclide supply. MRIP will run until March 2025 and has been designed around three core workstreams:
 - a) Landscape Assessment and Scenario Analysis HMG contracted with Ernst & Young LLP (EY) following a competitive process to take forward Phase 1 of this workstream. Under Phase 1, EY undertook a landscape assessment of medical radionuclide supply and demand. Phase 2 will commence later this financial year, aiming to forecast future supply and demand in the UK.
 - b) Legacy Nuclear Material Access The Nuclear Decommissioning Authority (NDA) has coordinated a review of the UK Radioactive Waste Inventory to identify materials with potential value for medicine and evaluate their accessibility.

¹ Supply of Medical Radioisotopes, POSTnote, 11 July 2017

The outputs from workstreams a) and b) are not currently publicly available but will be shared with Programme participants where there is significant value identified and the appropriate agreements are in place.

c) Innovation Project Workstream – the subject of this guidance. This seeks to provide funding to successful projects with potential to positively impact the UK's access to medical radionuclides in the future to support the identified growth opportunities. The design of this workstream, and the focus on Positron Emission Tomography (PET) and therapeutics, has been informed by three stakeholder workshops held on 27 February and 2 March 2023.

MRIP Innovation Project Workstream

- 5. HMG's assessment of the medical radionuclide landscape has identified two areas with significant clinical and market growth opportunities: notably, Positron Emission Tomography (PET) and therapy. The MRIP Innovation Project Workstream therefore aims to further the development of technologies and techniques that could support access to radionuclides for PET and/or therapies.
- 6. Up to £4 million of the total MRIP budget has been allocated for this workstream. HMG are seeking innovation projects requiring funding between £10,000-£500,000 (noting co-investment requirements set out later in this guidance). Proposals outside of this range will still be considered but a strong rationale will be required to justify the deviation from the suggested funding amounts.
- 7. Projects are required to focus on the following challenges relating to medical radionuclide production:
 - a) Developing new target enrichment and manufacturing techniques
 - b) Improving the outputs of existing irradiation techniques
 - c) Improving or developing radioactive material processing techniques

The table below provides more information on the focus of each of the challenges.

	Medical Radionuclide Value Chain Focus	Description
1	Target enrichment and manufacturing	 Target enrichment and manufacture happens in the early stages of the medical radionuclide supply chain. It is critical that access to suitable target materials is maintained, and enrichment and manufacturing capability grows with the increasing interest in new radionuclides for medicine. HMG is already aware of several radionuclides where supply is challenged by access to the appropriate target material. To that effect this challenge will focus on: Improving efficacy of enrichment/manufacturing processes for the targets of frequently used medical radionuclides.

	Medical Radionuclide Value Chain Focus	Description
		 Developing new enrichment and/or manufacturing routes for the targets of radionuclides of increasing interest for medical applications.
2	Improving the outputs of existing irradiation techniques	 There are several technologies that are/could be used to irradiate targets and produce the required radionuclides, these include but are not limited to research reactors and cyclotrons. Due to the scale of the fund HMG is not looking to fund the development of new irradiation technologies. Instead, this challenge will focus on: The application of existing irradiation techniques to produce "new" medical radionuclides. Improving the quality/yield of medical radionuclide produced using existing irradiation techniques.
3	Radioactive material processing	 HMG is also aware of increasing research in the extraction and processing of radioactive materials to ensure they are suitable for clinical and health research applications. This challenge will therefore focus on: Developing new routes for the extraction and/or processing of "new" radionuclides. Increasing the yield and purity of the radioactive material resulting from processing.

- 8. Following award, successful projects need to be completed by March 2025 at the latest. Projects do not have to run the full course of the programme.
- 9. Projects must be related to the provision of radionuclides for medicine and must meet the R&D criteria set out in the HMG Consolidated Budgeting Guidance 2023 to 2024². Please note that clinical research activities, such as the development of a new ligands, are out of scope, as are projects focused on developing novel irradiation techniques.

Objectives

Under the MRIP Innovation Project Call, HMG would like to achieve the following objectives:

- 1. Deliver a minimum of 4 innovation studies by March 2025 focussed on building capability that could improve UK access to medical radionuclides in the future.
- 2. Diversify existing capabilities/technologies in support of medical radionuclide production by March 2025.
- 3. Increase awareness of innovation and market opportunities in medical radionuclide supply by March 2025.

² Consolidated budgeting guidance 2023 to 2024, HMG, 13 March 2023

Alignment with other HMG programmes

10. HMG is currently also running the Nuclear Fuel Fund (NFF), the Future Nuclear Enabling Fund (FNEF) and the AMR Research, Design and Demonstration (RD&D) programme. Participation in any of these programmes will not affect the likelihood of an applicant being awarded funding through MRIP, however specific project deliverables which are already being supported through another programme will not be eligible for support from MRIP.

Application and Assessment Process

- 11. In this document, 'applicant' refers to either a single organisation or the lead applicant of a consortium.
- 12. Applicants must ensure they have read this guidance document in its entirety before applying.
- 13. The application and assessment process consists of the following stages:
 - In **Stage 1** the application window will be open from 31 May 2023 until 26 July 2023 at 12pm. Applicants are able to submit questions of clarification until Wednesday 21 June 2023 at 12pm. HMG will publish these questions and the relevant answers on gov.uk before the application window closes.
 - In **Stage 2**, applications will be assessed against the eligibility criteria. This assessment will include financial due diligence.
 - In **Stage 3**, applications deemed to be eligible will be evaluated against the detailed technical and deliverability criteria. Only those that meet the benchmark for this assessment will move on to the next stage.
 - In **Stage 4**, applications will then undergo an economic assessment. Applications must meet the benchmark for the economic assessment to proceed.
 - In **Stage 5**, shortlisted applications will then be subjected to an internal HMG assurance and approvals process, including a portfolio assessment if required.
 - In **Stage 6**, a grant offer letter will be sent to successful applicants and a grant agreement signed prior to the awarding of the grant's funds.

Stage 1: Application window open and preparation window

- 14. The timeline for applications is detailed below. HMG will not accept applications submitted after the advertised deadline. HMG retains the right to extend the application deadline, and other milestones, at any time and will communicate any changes via gov.uk in advance.
- 15. Stakeholders interested in the programme are invited to join a workshop in 1 Victoria Street, London, SW1H 0ET on 20 June 2023 at 1pm. This event will include an opportunity for prospective applicants to ask questions relating to the application guidance and a demonstration of how to fill out Annex 3 for the Economic Assessment. Stakeholders should register their interest in attending the event by emailing <u>MRIP@beis.gov.uk</u> by 12pm on 14 June 2023.

Milestone	Date
Application and clarification window opens	31 May 2023
Stakeholder workshop – Q&A on application guidance and demonstration of how to fill out Annex 3	1pm on 20 June 2023
Clarification window closes	12pm on 21 June 2023
Clarifications published	28 June 2023
Application window closes	12pm on 26 July 2023

- 16. Bids should be sent to <u>MRIP@beis.gov.uk</u> with the subject line "Application for MRIP Innovation Project Workstream" as a zipped folder attachment, by 12pm on 26 July 2023. Applicants should use their individual company/lead consortium email address as this will ensure that company details are securely held and accessed through this individual contact. Please use only one email for your application. If applying on behalf of a consortium, the covering email should include details of the other organisations involved.
- 17. The information provided will be handled in line with the Data Protection Act 2018 which is the UK's implementation of the General Data Protection Regulation (GDPR). HMG will hold your data for the period necessary for evaluation, monitoring and reviewing the MRIP against the objectives and benefits it is aiming to achieve.
- 18. Applicants will be notified once applications have been received by HMG and can expect to receive further updates once the application window has closed. Assessment of applications will only begin once the application window has closed.

19. HMG reserves the right to amend the enclosed public facing documents at any time prior to the closing of the bid window. Any such amendment will be numbered, dated and issued on gov.uk. Where amendments are significant, HMG may, at its discretion, extend the deadline for receipt of applications.

Application Cost Liability

20. HMG will not be responsible for any costs incurred in the preparation of any application, whether successful or not.

Requests for clarification

- 21. If applicants have any questions about the application and/or assessment process, they should submit their questions in writing to: <u>MRIP@beis.gov.uk</u>, clearly marked with "Request for Clarification" in the subject line, as soon as possible but no later than 12pm on 21 June 2023. Questions submitted after this deadline may not be answered.
- 22. HMG will aim to answer any questions which, in the judgement of officials, are of material significance. Answers will be publicly available through an anonymised clarification Q&A document published on gov.uk.
- 23. If an applicant considers that their question is confidential, they should make this expressly clear in the subject title of their email. Marking a question as confidential does not mean that HMG will withhold the question and response from other applicants or potential applicants; it simply means that HMG may redact or edit the response, if appropriate.
- 24. HMG will not provide advice on the content or structure of an application. The onus is on applicants to read and understand the requirements set out in this guidance document before submitting an application.

Documentation Required

The table below summarises the requirements for each stage of the assessment. More detail on these requirements is provided later in this guidance document.

Section	Required Documentation	Evaluation Approach
А	Eligibility and Financial Checks:	Pass/Fail
	 Completed eligibility questionnaire. Outline of consortia arrangements (if any), members, roles, governance arrangements, and structure. 	

Section	Required Documentation	Evaluation Approach
	Statutory accounts provided.	
В	Technical Assessment (40%):Written statement	Pass/Fail
С	 Deliverability and Project Controls Assessment (30%): Project execution and delivery plan Organisation/team structure as part of the project resourcing plan Waste management declaration (if relevant) 	Pass/Fail
D	 Economic Assessment (30%): Completed spreadsheet Any required evidence to support a Value for Money (VfM) assessment 	Pass/Fail
E	 Equality, Diversity and Inclusion: Breakdown of team working on the project and wider workforce in terms of protected characteristics Relevant organisational ED&I policies 	Not evaluated but used to support HMG Public Sector Equality Duty Assessment.
F	 Completed declarations: Statement of non-collusion Form of bid Conflict of interest 	Pass/Fail

- 25. The onus will be on applicants to provide all the required information and to answer all the questions within their application, in full. Applications that are incomplete or contain incorrect information may be rejected. Applications that do not meet the benchmark for any of the above assessments will not proceed to the next stage and the organisation will be notified.
- 26. HMG will accept documents in Microsoft Office or PDF document formats. Images may be provided in .jpg or .png format where appropriate.

Stage 2: Eligibility Checks

- 27. When the application window closes, HMG will undertake completeness checks on all applications to ensure that all the required information and accompanying documentation has been returned in full and that all relevant documents are accessible and legible.
- 28. All applications will initially be considered against the competition eligibility criteria. To be eligible for funding, proposals must meet all of the following eligibility criteria. These criteria are pass/fail and if a proposal fails any criterion, it will be removed from the assessment process. The applicant will be notified as soon as possible once the decision has been made to fail the application. Applicants should self-certify that they meet the following eligibility criteria.

Applicants Eligibility

UK Based

29. The successful entity (i.e., a sole applicant or lead member of a consortium) which enters into a Grant Funding Agreement must be a registered company in the UK under the Companies Act 2006 (CA06), unless the organisation is a UK public body. Applicants must confirm that they are already registered in the UK under the CA06, or able to make the necessary arrangements to do so by 1 September 2023, if their application is successful.

Offences

30. Applicants must confirm that neither the applicant (or none of the consortium partners if a consortium), nor any of its/their directors or officers, have been convicted of any of the offences listed under regulation 57(1) of the Public Contracts Regulations 2015. This also applies to any parent companies (as defined by section 1162 of the Companies Act 2006) of the applicant and any consortium member and to directors and officers of those parent companies.

Sanctions

31. Applicants must confirm that neither the applicant (or each of the consortium partners if a consortium), nor any of its/their directors or officers, are subject to United Nations, European Union, or United Kingdom sanctions. This also applies to any parent companies (as defined by section 1162 of the Companies Act 2006) of the applicant and any consortium member and to directors and officers of those parent companies.

Solvency

32. Applicants must confirm that the applicant (or each of the consortium partners if a consortium) is not in the situation described in Article 57(8)(b) of the Public Contracts Regulations 2015 (it is not the subject of insolvency or winding-up proceedings etc., or in any analogous situation arising from a similar procedure under the laws and regulations of any state). This also applies to any parent companies (as defined by section 1162 of the Companies Act 2006) of the applicant and any consortium member and to directors and officers of those parent companies.

Applicants should note that financial due diligence will be carried out.

Non-Proliferation

- 33. Applicants must confirm that the applicant (or each of the consortium partners if a consortium), and all entities in the upward group structure are associated with a country that has both signed and ratified the Treaty on the Non-Proliferation of nuclear weapons (NPT) and one of:
 - a) a Voluntary Offer Agreement (VOA);
 - b) a Comprehensive Safeguards Agreement (CSA);
 - c) a modified Small Quantities Protocol (mSQP); and
 - d) an Additional Protocol (AP) with the International Atomic Energy Agency (IAEA). The AP should be universal and supplementary to whichever of the three primary safeguards agreements the country has with the IAEA.
- 34. Applicants must also confirm that the applicant (or each of the consortium partners if a consortium), and all entities in the upward group structure are not associated with a country which is subject to United Nations, European Union, or United Kingdom sanctions due to infringements of the NPT, their CSA, or an associated Additional Protocol. In this context 'associated with' is defined as incorporated in, operating in, or owned (directly or indirectly) by nationals of this country.

Application Eligibility

35. Only those applications that a) meet the eligibility criteria and c) can demonstrate adherence to the points below, will be considered.

UK Benefit

36. HMG can only fund activities that provide Value-for-Money (VfM) to the UK taxpayer. Any technologies within the end-to-end demonstration chain must be located in the UK and over 50% of the project work (by value) should be conducted in the UK. There are no regional restrictions within the UK on where demonstrations can be located.

Project end date

37. The project must be completed, with evidence of all deliverables submitted to HMG, by 31 March 2025.

Alternative Public Funding

- 38. Applicants must indicate if they, their associated entities, or their consortium partners are participating in any similar activities that are funded elsewhere by HMG and/or another public authority in the UK, and/or another government.
- 39. In particular, applicants must state whether the project deliverables are already being funded by, or are in the process of applying for funding from, other HMG programmes, including but not limited to the Nuclear Fuel Fund (NFF), Advanced Modular Reactor (AMR) Research, Development and Demonstration Programme and the Future Nuclear Enabling Fund (FNEF). If the project deliverables are successful in receiving funding from another HMG programme, the applicant is required to notify HMG, and the project will be removed from the running for the MRIP.
- 40. This criterion does not exclude a single entity from proposing multiple projects, either for the MRIP or another HMG programme. If a single entity wishes to propose multiple discrete projects, each should be submitted as a separate application.

Eligible project costs

41. Eligibility requirements for costs are detailed in the table below. HMG will expect to see detailed underlying assumptions for all costs and explanations of how and why they are eligible. HMG reserves the right to ask for costs it deems ineligible to be removed from project costs.

Fair market value	Costs must be at 'fair market value'. Profit must not be included (including profit within labour costs).	
Directly attributable	e Costs must be directly attributable to the project.	
R&D expenditure	Costs must be capable of meeting R&D capital requirements set out in the HMG Consolidated Budgeting Guidance 2023 to 20242.	
Grant period	Costs must be both incurred and defrayed within the grant period (from grant award date to 31 March 2025).	
International accounting standards	Costs must be as detailed by UK FRS 1024 and/or international accounting and financial reporting standards.	

Cost limits

42. The proposed project must be within the specified cost limits for funding. HMG intends to fund multiple projects through the Innovation Call for Projects. The minimum amount of funding per project is £10k; based on evidence from the stakeholder workshops held in March 2023, HMG suggests a maximum individual grant size of £500k. HMG reserves the right to vary the amount of funding awarded, based on the merits of each project and its relevance to MRIP objectives.

Additionality

43. Applications must provide strong evidence that the project would not be taken forward, would otherwise take place outside the UK or would be taken forwards at a much slower rate, without MRIP funding. This evidence can be provided in Annex 3.

Finance

44. Applications must specify the total cost of the project, and the amount of funding being sought. Projects need to comply with requirements set out in the subsidy control Research, Development and Innovation Streamlined Route³. For larger projects, some level of co-investment will be required depending on the size of the enterprise applying and whether the applicant is applying on behalf of a single entity/consortium (more detail can be found in the section on subsidy control requirements later in this guidance). Please note that the grant award will be paid in arrears.

Terms and Conditions

45. Applicants must agree to standard grant terms and conditions in Annex 5.

Self-certification

46. If applicants have self-certified that the project meets the eligibility criteria, but crosschecks with other parts of the application leads HMG's assessors to believe that a project is not eligible, it may be excluded from further evaluation.

³ Research, Development and Innovation Streamlined Route, HMG, 13 December 2022

Stage 3 and 4: Evaluation

47. Eligible applications will be evaluated against a set of pre-defined criteria comprising three broad assessment strands – technical, deliverability & project controls and economic. Each strand is made up of a set of criteria and is weighted as follows:

Technical Assessment – 40% of overall score

Deliverability and Project Controls Assessment - 30% of overall score

Economic Assessment - 30% of overall score

48. For the Technical and Deliverability assessments, eligible applications will be assessed and scored from 1-10 against each of the criterion. The Economic Assessment will be scored using a different approach, as the VfM assessment will evaluate strength of evidence and the benefits associated with the proposed project. Each of these criteria have sub-criteria to indicate what the assessment panel will consider when awarding scores. To achieve the highest scores, proposals must provide high quality responses that; fully answer all parts of the criterion (i.e., which addresses all the sub-criteria); are detailed and fully evidenced; and justify any claims or assertions made.

Score	Completeness	Level of detail	Evidence/justification
1	Not answered	Superficial	Not evidenced/justified
2	Major omissions	Superficial	Lacking evidence/justification
3	Significant omissions	Superficial	Lacking evidence/justification
4	Significant omissions	Superficial	Partially evidenced/justified
5	Significant omissions	Reasonably detailed	Partially evidenced/justified
6	Minor omissions	Reasonably detailed	Partially evidenced/justified
7	Minor omissions	Reasonably detailed	Mostly evidenced/justified
8	No omissions	Reasonably detailed	Mostly evidenced/justified
9	No omissions	Very detailed	Mostly evidenced/justified
10	No omissions	Very detailed	Fully evidenced/justified

49. Applications will need to score more than a 4 for all scored assessments. Assessments will be carried out by HMG officials or by third-party contractors appointed by HMG with relevant expertise. The scores for each assessment will be moderated by an

evaluation panel chaired by an HMG official. Applications that score above the minimum threshold, in each criterion and overall, will be ranked for consideration for funding. A Technical Advisory Board (TAB) will also review applications and provide advice on each project's technical merits to the evaluation panel. Members of the TAB will be required to enter into a Non-Disclosure Agreement. They will not be permitted to sit on the formal evaluation panel and any conflicts of interest will be managed appropriately.

50. Before making a final decision, HMG may, at its discretion, contact applicants directly to request clarification on the information provided in their applications. It remains the responsibility of the applicant to ensure that all required information and documentation are included in the relevant sections of the application. Applicants will typically be given no longer than five working days to respond to requests for clarification.

Technical Assessment (40%)

- 51. Applications are required to demonstrate how the project will contribute to developing capability in medical radionuclide production or processing. As discussed above, HMG's assessment of the medical radionuclide landscape has identified two areas with significant clinical and market growth opportunities: PET and therapy. HMG are seeking R&D projects related to the following challenge areas across the medical radionuclide supply chain for PET and therapy:
 - a) Developing new target enrichment and manufacturing techniques.
 - b) Improving the outputs of existing irradiation techniques.
 - c) Improving or developing radioactive material processing techniques.
- 52. Applicants are asked to provide a written statement (maximum 5 sides of A4) which includes the following:
 - A technical summary of their proposed innovation project.
 - The main technical challenges they seek to overcome and significance in the medical radionuclide supply chain.
 - The main technical risks associated with the design and how they plan to mitigate these.
 - An evaluation of how the project will contribute to the above challenges and MRIP objectives set out earlier in this guidance.
 - Evidence of how the project will contribute to social value via supporting skilled jobs across the UK and increasing capability and knowledge across the supply chain.

Deliverability & Project Controls Assessment (30%)

- 53. The objective of the Deliverability and Project Controls Assessment is to examine the deliverability of applications and the impact of the outputs. Applicants should provide the following information on no more than 5 sides of A4.
- 54. The Deliverability Assessment will be comprised of three sub-criteria (criteria a and b are equally weighted, c will not be scored but should be completed):
 - a. Project Execution and Delivery Plan

Proposals will be scored on the suitability and credibility of the project delivery schedule, milestones, deliverables, approach to risk management and processes for governance/project management.

The programme has been designed to build an evidence base for future HMG decision making on matters related to medical radionuclide access in the UK. Projects should therefore be designed to provide HMG with a short interim report in July 2024, if not finished by then.

b. Resourcing

Proposals will be scored on the qualifications and expertise of the project team as well as the project team's access to cross-functional expertise.

c. Radioactive Waste Management Declaration

This section will not be scored but applicants that expect to produce waste streams as a result of the proposed project must declare that these would be managed in line with current regulatory and policy requirements.

Economic Assessment (30%)

- 55. The objective of the Economic Assessment is to evaluate the VfM of the project and maximise benefits in line with Green Book methodology.
- 56. The Economic Assessment will comprise of a VfM assessment, including the appraisal of research impacts and benefits. Applications will be scored on the VfM presented for the project, which takes into account the breakdown of the eligible cost schedule, cost justifications, benefits and supporting evidence.
- 57. This criterion will be assessed through a separate spreadsheet (Annex 3) and will be evaluated by a different team to those conducting the Technical and Deliverability and Project Controls Assessments.

Stage 5: MRIP Portfolio Assessment

- 58. HMG reserves the right to take a 'portfolio approach' to awarding funding. If enacted, this assessment will be used to ensure a suitable spread of projects are supported across all three of the challenge areas discussed earlier in this guidance. It is intended to avoid duplication and facilitate decisions on priorities should projects score the same during evaluation.
- 59. If a portfolio assessment is required, it will follow the application evaluation and score moderation. The evaluation panel will then evaluate the proposals to determine whether a suitable portfolio has been selected and will retain the right to override the order of ranked proposals if appropriate. The portfolio approach will only be enacted where portfolio decisions could drive diversity in the technology options being considered under MRIP.

Stages 6: Final Decisions on Award

Embargo - decisions on award

60. Please note that there will be an embargo placed upon the details of shortlisted projects until HMG has made the formal offer of grant funding announcement. Applicants must not publish any outcomes of the assessment process without HMG's express permission. Where an applicant does so, it may jeopardise their continued role in the process and HMG reserves the right to disqualify or reject any applicant that breaches this requirement.

Notification of applicants

61. Applicants will be informed by email as to whether their application has passed the evaluation stage. An application shortlisted at this stage does not constitute grant award, which will be subject to internal HMG assurance and approvals processes and due diligence.

Decision on successful applicants

62. After the conclusion of final checks, senior officials will be presented with the full results of all assessments and considerations to make a final decision regarding successful applicants. Final checks include the eligibility checks, financial due diligence, evaluation, subsidy control compliance checks, PSED considerations and – if enacted – the portfolio assessment.

Internal HMG assurance and approvals processes

63. Prior to grant award, shortlisted applications will be subject to internal HMG assurance and approvals processes. Further information may be requested from applicants to support these processes. Senior officials will have the final say on projects that are awarded grants.

Grant award

- 64. If the results of the assessments and internal HMG approvals processes are satisfactory, applicants will be issued a grant offer letter including standard terms and conditions. This must be signed and returned to HMG within five working days of receipt. Applicants must ensure compliance with conditions contained in the offer letter and agreement to receive grant funding. HMG will not negotiate on the value of the grant once awarded.
- 65. The grant offer letter will be drafted in line with standard departmental grant offer letter terms and conditions, modelled on the Cabinet Office's Guidance for General Grants⁴. The terms of the grant offer letter are not negotiable. HMG reserves the right to adapt the terms of the offer letter and agreement in respect of the relevant project.
- 66. In the event an applicant refuses to agree to the terms of the offer letter or unduly delays the process, HMG reserves the right to withdraw the offer letter. In this circumstance, the application will be deemed to have been disqualified from the process.
- 67. Senior officials will retain full discretion over whether, and what, offers of public funds they make to applicants, taking into account all the factors outlined in this document.

Publication of successful projects

- 68. At the end of the application and assessment process and upon signing of the grant funding agreement, HMG may communicate which projects have been successful through media engagement, issuance of a press release or publication notice on gov.uk.
- 69. Awards will need to be published on Grants Finder and awards above £100,000 from the fund will need to be published on the subsidy transparency database. It is not possible to opt out of this. Details published include (but are not limited to):
 - a) the identity of the applicant and consortium members (if applicable);
 - b) project summary information including aims and expected outcomes of the project, long-term project and technology area; and

⁴ Guidance for General Grants, HMG, 31 August 2021

c) total award value.

Important information for applicants

Applications from Consortia

- 70. Applications will be accepted from consortia and partners, as well as individual organisations. In the case of an application from a consortium, only one application covering all consortium partners is required. The application must outline:
 - a) which consortium partner is the lead applicant; and
 - b) the proposed role that each consortium partner will play in executing the project.

Applications should set out the organisation and governance of the consortium.

- 71. It is anticipated that HMG will only enter direct arrangements with the lead applicant of a consortium, with the lead applicant responsible for the dispersal of funds, management of consortium partners and recovery of any misused funds by any consortium partners. The lead applicant should therefore be of suitable size and capability to represent a viable entity to lead on projects.
- 72. HMG recognises that arrangements in relation to consortia may (within limits) be subject to future change. Applicants should therefore set out arrangements as currently envisaged. Applicants should note that, should they be successful in applying for funding as the lead applicant of a consortium, any future proposed change in relation to membership of that consortium must be submitted to HMG for approval.

Subsidy control assessment

- 73. Please note, it is the responsibility of the applicant/s to ensure that they meet the eligibility criteria and comply with the subsidy control rules that are applicable to their project and organisation (or consortium). Our support will be delivered as Minimal Financial Assistance (MFA) wherever possible for grants up to £315,000 and applicants should familiarise themselves with this provision. Where grants exceed this limit and it is not possible to deliver it as MFA, it will be delivered under the subsidy control Research, Development and Innovation Streamlined Route. Grants will only be awarded where they either meet the requirements of MFA or Research, Development and Innovation Streamlined Route may result in the subsidy being clawed back or other sanctions being imposed.
- 74. Compliance with subsidy control requirements is an important part of the assessment process and will be considered during all the assessment stages. Due to the size and nature of this programme, subsidy control assessments will be completed under the MFA or the Research, Development and Innovation Streamlined Route.

- 75. Applicants should refer to the following documents to support a complete and accurate application submission:
 - Statutory Guidance for the United Kingdom Subsidy Control Regime: <u>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attac</u> <u>hment_data/file/1117122/uk-subsidy-control-statutory-guidance.pdf</u>
 - Research, Development and Innovation Streamlined Subsidy Scheme: <u>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attac</u> <u>hment_data/file/1128056/research-development-innovation-streamlined-route.pdf</u>
 - Research, Development and Innovation Streamlined Route Guidance: <u>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attac</u> <u>hment_data/file/1128060/research-development-innovation-streamlined-route-guidance.pdf</u>

Subsidy Eligibility Criteria

- 76. Applicants that are not eligible for MFA must determine whether they meet the subsidy eligibility criteria set out in the Streamlined Route guidance for the Research, Development and Innovation category. This will include ensuring that any bid does not exceed the relevant subsidy threshold as set out in the guidance (i.e., small/medium/large enterprises are eligible for up to 70%/60%/50% of eligible project costs respectively).
- 77. In all cases, applicants **must** be able to demonstrate that the subsidy is necessary to deliver the project and is proportionate to its objectives.

Calculating Subsidy Ratios

- 78. Applicants **must** provide a full breakdown of costs associated with the project alongside the application to determine the subsidy ratio. This must contain:
 - a) **Personnel costs** meaning a full breakdown of those involved in the project. This includes roles, estimated hours or days to be contributed, salary rates or rates based on industry benchmarks.
 - b) **Equipment and material costs** meaning the equipment and materials required for the project, their estimated costs and their relevance to the project's objectives.
 - c) **Subcontracting costs (if applicable)** meaning details of any subcontractors involved in the project, including roles and estimated cost of services.
 - d) **Consultancy costs (if applicable)** meaning the scope of external consultancy work, estimated costs and their contribution to the project's success.
 - e) Other project-related operating costs meaning costs directly linked to the project. This may include travel expenses, software licenses, consumables, or overhead costs, and any information on previous subsidies received for the same project, as well as their source and amount.

The assessing authority will use this information to calculate the relevant subsidy ratio. It is crucial for applicants to provide all the necessary information for this to be done accurately.

Applications in scope of the Windsor Framework

- 79. Applicants will be subject to Article 10 of the Windsor Framework (WF) if they are conducting activities that affect trade in goods or electricity between Northern Ireland and the European Union as envisaged by Article 10. This is most likely to apply to applicants and partner organisations based in Northern Ireland, but in limited circumstances may also affect those in England, Scotland, Wales and those based internationally.
- 80. Applicants must answer some questions as part of their application (Annex 1), that will help HMG determine whether they are likely to be subject to Article 10 of the WF. The questionnaire has a yes / no format and applicants should consider the activities of their business in its entirety and project partners when answering. If an applicant's response to the questionnaire indicates that they are in scope of the WF, HMG will ask further questions. These additional questions will differ according to the location of businesses.
- 81. If an application is successful and HMG determines that this application engages Article 10 of the WF, HMG will engage with the applicant prior to issuing a grant offer letter to ensure that any grant offered is compliant with State aid obligations under Article 10. Mitigations to an application falling within scope of the WF could include the application of the General Block Exemption Regulation, exploring opportunities to eliminate cross-subsidies to Northern Ireland by requiring applicants to ringfence subsidised activities as a condition of the grant award, or making a formal State aid notification to the European Commission.

Eligible Costs

82. Applicants must ensure that all costs included in their application adhere to the eligibility criteria outlined in the guidance. It is important to note that eligible costs may vary depending on the chosen category and may be subject to specific limitations or restrictions. Therefore, applicants should thoroughly review their project plan and make any required adjustments if they intend to seek a subsidy through a category with such limitations. It is crucial that project plans are aligned with the specified eligible cost criteria provided in the category guidelines before submitting to avoid any delays in the application process.

Cumulation

83. Applicants should confirm with the intended subsidy recipient if they have received any other form of subsidy from another public authority for the same project to achieve substantially the same policy objectives. If they have, then they will need to follow the

cumulation steps as set out in paragraph 6.23 of the Research, Development and Innovation Streamlined Route guidance.

Transparency Requirements

84. If the subsidy awarded is over £100,000, it is the duty of the public authority to upload it onto the UK subsidy database. Applicants should be aware of the transparency requirements and ensure that they comply with them.

Public Sector Equalities Duty assessment

- 85. To fulfil requirements of the Equality Act (2010), HMG is required to have due regard to the Public Sector Equality Duty (PSED). This includes having due regard to the need to:
 - a) eliminate discrimination, harassment, victimisation, and any other conduct that is prohibited by or under the Equality Act 2010;
 - b) advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it; and
 - c) foster good relations between persons who share a relevant protected characteristic and persons who do not share it.

Protected characteristics include:

- a) age;
- b) disability;
- c) gender reassignment;
- d) marriage and civil partnership;
- e) pregnancy and maternity;
- f) race;
- g) religion or belief;
- h) sex; and
- i) sexual orientation.
- 86. In addition to the information requested to inform the Economic Assessment, applicants are also requested to provide a breakdown of their workforce based on the above protected characteristics and the relevant organisational Equality, Diversity and Inclusion policies. These additional documents will not be scored but the information will assist HMG in conducting a PSED assessment. The onus of conducting a PSED assessment is on HMG, not the applicant. However, completion of the PSED section of the application is not optional and applicants are required to provide all the information requested unless there are legal restrictions on the applicant's collection of the requested data.

Terms and conditions

Standard terms and conditions

87. The terms and conditions for awards from the fund will be drafted in line with the standard departmental terms and conditions, modelled on the Cabinet Office's 'Guidance for General Grants'. The standard terms and conditions are non-negotiable. HMG reserves the right to adapt the terms and conditions in respect of the relevant project.

The full standard terms and conditions for an award are set out in Annex 5.

Intellectual property rights

- 88. The proposed arrangement for intellectual property rights is set out in Annex 5.
- 89. As per these conditions, the output of the project in receipt of funding will be the property of the recipient, with the recipient granting the Secretary of State a non-exclusive irrevocable and royalty-free, sub-licensable, worldwide licence to use all the intellectual property material for the purpose of supporting the funded activities and other projects.
- 90. Costs associated with securing intellectual property arising from, or associated with the project, will not be eligible for reimbursement.

Privacy notice

91. The Department for Energy Security and Net Zero's privacy notice can be found in Annex 6. Applicants should confirm in their application (Annex 1) that they agree to the attached privacy notice.

Information disclosure

- 92. All information provided as part of an application, including personal information, may be disclosed in accordance with any applicable law (including the Freedom of Information Act 2000 and the Environmental Information Regulations 2004), by order of a court or as required by any body or inquiry which has the power to compel disclosure.
- 93. HMG will process personal data in accordance with all applicable data protection laws. If applicants want the information provided as part of their applications to be treated as confidential, they should inform officials, but they should be aware that HMG cannot guarantee confidentiality in all circumstances. An automatic confidentiality disclaimer generated by an applicant's IT system will not be regarded by HMG as a confidentiality request.
- 94. Where any request is made to HMG under the Freedom of Information Act 2000 for the release of information relating to any applicant or application, which would otherwise be reasonably regarded as confidential information, HMG will notify applicants of the

request as soon as reasonably able to. Applicants must acknowledge that, while they may deem any information or data confidential or commercially sensitive, HMG may nevertheless be obliged to disclose this information which applicants consider confidential.

95. Applications will be assessed by HMG officials or by contracted delivery partners. All assessors will adhere to confidentiality requirements and must declare any potential conflicts of interest. They will treat applications in the strictest of confidence and adhere to relevant data protection laws. HMG will not disclose the names of assessors to applicants.

Non-disclosure agreements

96. HMG will not, at this time, enter into non-disclosure agreements with applicants in relation to their applications or projects. Successful applicants to the fund with existing non-disclosure agreements must agree to waive all duties, obligations, commitments, undertakings, guarantees, warranties and liabilities owed or given by HMG or the Secretary of State under any such non-disclosure agreements in respect of the publication requirements set out in this guidance document.

Reserved rights

Withdrawal or amendment of fund

97. HMG reserves the right to withdraw or amend the scope of the fund without notice at any time and will not be liable for any costs incurred by applicants during any stage of the process.

National security

98. HMG reserves the right to disqualify any bid for a project that would in any way present a security concern to the United Kingdom.

Post-award monitoring process

- 99. Monitoring and evaluation activities of those projects receiving funding will be undertaken during the agreed funding period. Each funded project will have a monitoring officer allocated by HMG and be required to undertake regular, at least monthly, project reporting, to which officials will have access.
- 100. HMG will monitor delivery of the project to ensure compliance with the grant agreement and progress against the output indicators throughout the monitoring period. This will include funding claims, reviewing evidence of defrayed expenditure and ensuring compliance with subsidy control requirements. Monitoring could also include visits and monitoring information (including data on expenditure, progress with innovations, supply chain engagement, co-investment achieved) will be recorded on a centralised, web-based Management Information System.

101. HMG will agree core compliance indicators with each successful applicant. These will be based on the individual objectives of each project and may therefore vary for each successful applicant.

Payments

102. Payments will be made quarterly, in arrears, throughout the lifetime of the project, in line with Schedules in the grant offer and terms and conditions (Annex 5).

Detailed information requirements by section

- 103. Applicants should take note of the page limits for each section. Submissions should use Arial font in size 10. Applications that alter the margins or other formatting of the application form may be disqualified. Assessors will ignore any text which exceeds the page limit for each section.
- 104. Applicants should note that different sections may be evaluated by different assessors.

Section A: Eligibility & Financial Information

- 105. Applicants must complete and return the Eligibility Checklist in Annex 1. Applicants must agree with the department's privacy notice and confirm eligibility to apply for the fund. Applications which fail any of the eligibility checks will not be evaluated further.
- 106. Applicants must provide the information set out below on the structure and governance of the applicant. The applicant is not required to provide details for the entire supply chain. Information should be provided in Annex 1. The applicant should engage with officials if any confusion arises on the scope of this section.

Applicants must provide the following information:

- a) full name of the organisation;
- b) UK company registration number (of the consortium lead);
- c) registered address;
- d) company website;
- e) company NACE code (NACE refers to the European Classification of Economic Activities⁵);
- f) total number of FTE employed by the applicant (please see below for the definition of FTE);
- g) the latest statutory accounts covering 3 years of results (full set with notes) for the applicant and ultimate parent; and,
- h) if the applicants statutory accounts are more than 6 months old, applicants should provide draft statutory accounts or management accounts. This is not necessary for the ultimate parent.
- 107. The applicant must state how many people are employed in the entire Group. This information is required from all consortium partners as well. FTE refers to the

⁵ For further guidance on NACE, please see <u>NACE Rev.2.</u>You can search for your company's NACE code on <u>Eurostat</u>.

number of Full Time Equivalent employees (FTE). Please note an FTE job is one of 30 or more hours per week. If the role requires any additional hours this still only counts as 1 FTE. Two part time jobs of 15 hours or more count as equivalent to one full time job. Any part time jobs of 15 hours up to 30 hours should be stated as 0.5 of an FTE.

- 108. Applicants must provide the project director's contact details, including their name, telephone number and email address. Applicants must also provide the same details for a lead contact as well as an alternative contact in the event that the lead contact is unavailable.
- 109. If the applicant is a consortium, they must outline the membership and roles of each member in the consortium. They must indicate who in the consortium is authorised to be the lead contact, and the organisational and governance arrangements associated with that consortium. Please include the proposed role that each partner will play in the project.
- 110. Applicants must provide information on whether the applicant or members of the consortium has received other public sector funding in the last three years including the following:
 - a) details on the name of fund or scheme that provided the funding;
 - b) the name of the body or HMG department that awarded the funding;
 - c) how much funding was awarded;
 - d) when the award was made; and
 - e) any existing conditions from this award that you are still committed to.
- 111. Applicants are also required to answer questions relating to the Windsor Framework in this section.
- 112. This section will not be evaluated but will be used to support financial due diligence.

Section B: Technical Assessment

- 113. Applicants should provide a written technical overview (no more than 5 sides of A4) of their proposed project including:
 - a) A technical summary of their proposed innovation project.
 - b) The main technical challenges they seek to overcome and significance in the medical radionuclide supply chain.
 - c) The main technical risks associated with the design and how they plan to mitigate these.
 - d) An evaluation of how the project will contribute to the above challenges and MRIP objectives set out earlier in this guidance.

- e) Evidence of how the project will contribute to social value via supporting skilled jobs across the UK and increasing capability and knowledge across the supply chain.
- Any other technical information that the applicant deems important to demonstrate adherence to project inclusions / exclusions and MRIP objectives.

Section C: Deliverability and Project Controls Assessment

114. Applicants must provide a narrative return in no more than 5 sides of A4 (including appendices) detailing the approach to delivery of the proposed project and controls in place. Summaries of the following requirements will be accepted if the full version exceeds the above page limit.

Section C.1: Project Schedule and Delivery Plan

- 115. The applicant must demonstrate:
 - a) a defined project scope with clear objectives, and benefits/deliverables that will be achieved by March 2025;
 - b) a credible project plan of how this will be achieved. This must include a project schedule, with workstreams and high-level milestones clearly identifiable and a more detailed task breakdown, which outlines the resource and costs of these activities;
 - c) details of the governance and controls that will be followed through the project, including the process for reporting to HMG;
 - d) identification of key stakeholders and a high-level stakeholder management strategy;
 - e) key known project assumptions, dependencies and constraints; and,
 - f) identification of top five risks associated with the proposed project, their likelihood and severity and any mitigations/planned responses.

Section C.2: Resourcing

- 116. This section should detail resourcing plans in place to deliver the proposed project. The applicant must demonstrate:
 - a) an Organisation Breakdown Structure of the project team, including clear team roles and responsibilities, reporting lines and relevant qualifications and expertise needed in teams. This can be provided as a separate Word, PDF, Excel, MS Project or other file, not subject to the page limits;
 - b) resource forecasting for the project, including labour, specialist or technical support, materials, equipment, facilities, admin, subcontractors, etc. for the duration of the project; and
 - c) plan to manage and control resource throughout the project.

Section C.3: Radioactive Waste Management

117. If the proposed project produces waste streams, applicants are required to confirm that management of the waste forms produced will comply with current regulatory and policy requirements.

Section D: Economic Assessment

- 118. Applicants must complete Annex 3 in full. Guidance on how to complete the template is included in the Excel file. Applicants must use the template to provide economic information on:
 - a) project summary;
 - b) itemised list of planned expenditure;
 - c) annual profile of expenditure;
 - d) wider benefits;
 - e) innovation and additionality; and,
 - f) co-investment (if applicable).
- 119. Applicants must provide evidence to support any numbers provided and the underpinning assumptions made. Applicants must therefore provide detailed estimates, evidence and a narrative to justify each cost and benefit (as required in the Annex 3). Evidence can be provided as a separate Word, PDF, Excel, MS Project or other files, not subject to page limits. It should be clearly named.
- 120. All costs, whether in respect of the project or any counterfactual, should indicate any risk factors applied and assumptions made, and should relate to the information supplied to the ultimate decision maker and the parent/group policies relating to how investment decisions are made by the organisation(s) undertaking the project.
- 121. All cost and price estimates presented in the template should be in GBP and in current 2023 prices. If converting values from another currency, applicants must provide evidence of the price/cost estimate in the original currency and supply the exchange rate used to convert the values to GBP.
- 122. Applicants should also specifically address how they account for macroeconomic uncertainty, especially the potential impact of inflation on the project in the 'Itemised list of expenditure' worksheet. Inflation will likely also impact benefit estimates, and this should be reflected in the 'Jobs', 'R&D details', 'Training' and Wider benefits' worksheets.
- 123. Applicants must include evidence to support cost and benefit estimates provided for the economic assessment. This could include but not be limited to details of the investment criteria that senior decision makers/executives will apply when making the

investment decision concerning the project. Other acceptable forms of evidence could include, but are not restricted to:

- a) who the ultimate decision-makers are regarding the proposal's work programme;
- b) what information is presented to relevant decision-makers, and how a decision will be reached;
- c) the metrics that the final decision-makers will use to compare any proposed options;
- d) parent/group policy or guidance documents relating to how investment decisions are made;
- e) any existing parent/group investment appraisal documents;
- f) extracts from Board papers/minutes where the different location options have been discussed (if this is relevant to the counterfactual);
- g) feasibility studies on the different options (internal or external) to the extent relevant to the project or the counterfactual;
- h) communications from Senior Executives to the extent relevant to the project or the counterfactual;
- i) precedents set previously with similar type/scale investment decisions; and
- j) evidence that ultimate decision makers are giving serious consideration to other options (including the option to not undertake the work).

124. The viability of alternative counterfactuals can be demonstrated by the following evidence:

- a) certified minutes from board-level meetings that discuss the alternative location;
- b) feasibility studies carried out by the counterfactual (or a third party);
- c) evidence of similar projects;
- d) communications from the decision-maker requesting cost reductions or directly addressing the capability of the counterfactual option; and
- e) location studies and relevant analysis feeding into board papers, etc.
- 125. Historic evidence that the metrics used for the decision-making process have been used previously by the applicant and are in line with wider company policy can help provide weight to any counterfactual and cost-gap calculation. This can come in the form of extracts from company policy or previous decisions that demonstrate the metrics and calculations reflect the applicant's standard practice.

Section E: Applicant Equalities Information

126. Applicants must provide the information set out below to support HMG in having due regard to its PSED duty. Information should be provided in Section E of Annex 2

or where appropriate as a separate document clearly labelled. There are no page limits for this return.

- 127. Applicants must provide the following information:
 - a) a complete breakdown of the applicant's, and consortium partners', if applicable, workforce for each protected characteristic outlined above;
 - b) supporting information, such as the applicant's, and consortium partners', if applicable, company equality, diversity and inclusion policies, commitments and targets, can also be included as annexes and uploaded to the Applicant Portal under the same heading;
 - c) an explanation of how the proposal could benefit or disadvantage each group of people with protected characteristics, including mitigations if a disadvantage is identified;
 - d) A demonstration of how the applicant and consortium partners, if applicable, will ensure their approach to equality and diversity is sufficiently robust to prevent discrimination, advance equality of opportunity amongst those with and without protected characteristics and foster good relations between those with and without protected characteristics;
 - e) An estimate of how many jobs this project will support, and the breakdown of these by protected characteristic; and
 - f) Any information applicants can provide regarding the impact the proposal may have on the three aims of the equality duty (i. eliminating discrimination, harassment and victimisation; ii. advancing equality of opportunity between those who share a protected characteristic and those who do not; and iii. fostering good relations, particularly in relation to those who share a protected characteristic and those who do not).
- 128. This section will not be evaluated; however, HMG anticipates there may be significant overlap between the content of this section and the questions asked as part of the Economic Assessment. The Economic Assessment will be evaluated.

Section F: Declarations

129. In addition to the declaration section in Annex 1, applicants are also required to complete the declarations in Annex 4.

This publication is available from: www.gov.uk/government/publications/medical-radionuclide-innovation-programme

If you need a version of this document in a more accessible format, please email <u>alt.formats@beis.gov.uk</u>. Please tell us what format you need. It will help us if you say what assistive technology you use.