NERA
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The economic impact of ONR safety regulation: Final Report

The Office for Nuclear Regulation

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Project Team

Project Team

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Executive Summary

This report, commissioned by the UK's Office for Nuclear Regulation, assesses the economic impact of UK civil nuclear safety regulation. The specification for this work asks for "qualitative and quantitative judgments supported by evidence on issues including:

- The degree to which economic considerations are built into the UK health & safety regulatory system and provide safeguards against disproportionate regulation;
- The extent to which, and why duty holders use quantitative and qualitative methods to demonstrate that they have met their legal duty to reduce risks SFAIRP".[1]

The study draws on the extensive published literature. It has considered the institutional structure and the incentives facing ONR and its inspectors. Most importantly it draws on the views of inspectors and regulated bodies across all ONR civil operational safety programmes. These exchanges have focused on the interactions between ONR and those whom it regulates and the consequent safety and other economic impacts, including the handling of balances between the benefits and costs of risk reduction.

We have reviewed ONR's activities across four of its six key operational programmes as of November 2016[2]:

- Sellafield, Decommissioning, Fuel and Waste;
- Operating facilities;
- New reactors;
- Cross ONR (focusing on Radioactive Materials Transport).

One of our key findings is that ONR is an impressive safety regulator. It appears to be fully meeting its primary responsibility to the nation, as an effective enforcer of nuclear safety regulation. This safety achievement is of great value. But for several reasons it cannot be sensibly monetised. Individual regulatory decisions and regulatory conventions and processes can however be assessed against the criterion of optimisation in the public interest. We have therefore focused on the individual operational programmes, gathering information in particular about how they each view the trade-offs between regulatory costs and benefits and how they strike the balance between them.

Some of the key findings for individual operational programmes are:

- The reformed regulatory structure and culture at Sellafield since April 2014 is making a major contribution to productivity at that site, relative to previous years. The discipline of a centrally-determined budget for the entire operation (administered

[1] This report was originally commissioned in early 2016, when most of the primary interviews were completed. The report was subsequently updated during the first half, and then the second half, of 2017, following successive further input from senior ONR management.

[2] The other two programmes are civil nuclear security, which is explicitly outside the scope of the study, and the activities of the Assurance, Policy and International Directorate, which initiated and funded the present work.

through NDA funding), combined now with a sustained relationship of trust and respect between regulator and licensee, appears to encourage efficient regulation.

- Nuclear transport regulation has recovered from extended transitional difficulties before and after its transfer from DfT to ONR.
- Across other programmes licensees report good professional relationships with the senior inspectors with whom they are dealing. And it appears that the regulatory fees of ONR, for reactors and other operating facilities, are significantly less than those in the US. This is likely to be due at least in part, however, to some of the analytical burden for ensuring safety being shifted from the operator to the regulator in the US, because of its prescriptive approach to safety regulation.
- The principle of generic assessment behind the GDA process is widely recognised as a good one, likely to result in cost savings over the long term. There are, however, concerns that the implementation and application of the new reactor programme to the current new reactor designs and projects could be more economically efficient.
- Some concerns were also identified in non-nuclear transport, which is one of the few areas subject to ONR regulation that includes SMEs. Another issue arising with non-nuclear transport is that ONR charges seem likely to end package development by at least some UK SMEs.

Overall, across its operations, we find that there would be scope for further improving ONR's economic impact. Potential areas for consideration include:

1. encouraging more external comment and comparisons;
2. more effective promotion and monitoring of the enabling regulation initiative;
3. improving ONR's knowledge of the costs imposed by regulatory decisions;
4. the use of economic advice in the framing and assessment of some issues; and
5. refinement of its current guidance on SFAIRP and gross disproportion.

Abbreviations

ABWR	The Advanced Boiling Water Reactor supplied by Hitachi-GE
AGR	Advanced Gas Cooled Reactor: UK designed civil reactor brought into commercial operation in the period 1985 to 1989
ALARP	As Low As Reasonably Practicable
AP1000	The PWR supplied Westinghouse
ASME	American Society of Mechanical Engineers
BSL	Basic Safety Level (mSv/year), usually a legal upper limit of radiation exposure
BSO	Basic Safety Objective (mSv/year), a very low 'broadly acceptable' level
CBA	Cost Benefit Analysis, in the convention sense of comparing monetised costs and benefits
CNSC	Canadian Nuclear Safety Commission
COCO-2	An NNI-commissioned assessment of the monetisable impacts of a major nuclear accident
COMAH	Control of Major Accident Hazards
EDF	EDF Energy (wholly owned by Électricité de France)
EDF-NGL	EDF Energy Nuclear Generation Ltd
EDF-NNB	NNB Generation Company Ltd (NNB GenCo), a Nuclear New Build subsidiary of EDF
EPR	The PWR supplied by Électricité de France
GD	Gross Disproportion
GDA	Generic Design Assessment of a proposed reactor design new to the UK
HSE	Health and Safety Executive
ICRP	International Commission on Radiological Protection
IA	[regulatory] Impact Assessment
INS	International Nuclear Services
IRPCG	Industry Radiological Protection Co-ordination Group
LC	Licence Condition (applying to the 36 ONR nuclear license conditions)
MDEP	OECD Nuclear Energy Agency Multinational Design Evaluation Programme
NDA	Nuclear Decommissioning Authority
NGL	see EDF-NGL
NII	Nuclear Installations Inspectorate
NNB	see EDF-NNB
NRC	United States Nuclear Regulatory Commission
ONR	Office for Nuclear Regulation
PWR	Pressurised Water Reactor
R2P2	'Reducing Risks, Protecting People' (HSE, 1999, revised 2001)
RMT	Radioactive Materials Transport
RP	Requesting Party, applied to reactor suppliers requesting a GDA
SAPs	Safety Assessment Principles for Nuclear Facilities (ONR)
SDF	Safety Directors' Forum
SFAIRP	So Far As Is Reasonably Practicable
SME	Small or medium size enterprise
Sv	Sievert, SI unit of effective radiation dose used in most developed countries
TAG	Technical Assessment Guide (ONR)
TIG	Technical Inspection Guide (ONR)
TOR	'The tolerability of risk from nuclear power stations' (HSE, 1988, revised 1992)
WENRA	Western European Nuclear Regulators' Association

1. Introduction

1. This report, commissioned by the UK's Office for Nuclear Regulation, assesses the economic impact of UK nuclear safety regulation. This includes the regulation of new nuclear build, operating reactors, other operating facilities, decommissioning, waste and radioactive materials transport.

2. The specification for this work asks for "qualitative and quantitative judgements supported by evidence on issues including:

   - The degree to which economic considerations are built into the UK health & safety regulatory system and provide safeguards against disproportionate regulation;
   - The extent to which, and why duty holders use quantitative and qualitative methods to demonstrate that they have met their legal duty to reduce risks SFAIRP;"

3. The main, though not exclusive focus is therefore on nuclear industry operators and suppliers, in the private sector or owned or contracted by the Nuclear Decommissioning Authority, but it also considers the effects of nuclear regulation on the public and the wider UK economy. It considers ONR interfaces with central government, the NDA, the HSE and the Environment Agency, ONR policies and guidance, and general government policies on better regulation. Reference is also made to other regulatory systems.

4. This study's scope excludes defence, the health sector, research applications of radioactive material, and security. It also excludes knock-on effects of regulation such as insurance / liability.

5. We interpret "economic impact" broadly, to include impacts on UK GDP, but also wider international impacts and any significant welfare impacts that would properly be included in the formal analysis of any major public policy.

6. The breadth and depth of ONR's responsibilities and technical expertise are daunting. We have however sought to understand and draw conclusions mainly by:

   i. Studying selected literature, initially and throughout the project;

   ii. Developing our own perspectives on questions such as the socio-political case for strong nuclear safety regulation, ONR incentive structures, and the current handling of and guidance on risk/cost trade-offs;

   iii. Speaking with a broad selection of inspectors and regulated bodies, and other public bodies. These discussions have focused on ONR's work in practice, particularly on the interactions between ONR and those whom it regulates, and the consequent safety and other economic impacts. We assess and report on what these responses imply.

7. Our assessments are made from the perspective of applied economics and experience of public administration. Our project team includes engineering qualifications and experience, but we make no assessment at all of the technical analysis that is central to much of ONR's work. We do however report on what others have told us in that context, and we do examine and comment on the incentive structures that may influence how ONR's technical analysis is applied, and on issues of regulatory culture.

8. The project specification asks for the study to report on the balance between optimal and excessive regulation, including:
   - the degree to which industry investments are affected by the direct costs of regulation
   - indirect costs flowing from regulatory requirements
   - the extent to which measures required by the regulatory system would be adopted anyway for commercial reasons
   - costs averted through effective regulation, including those associated with major accidents
   - the contribution of regulatory requirements, including post-Fukushima modifications, to new build cost escalation
9. Precise quantification of these effects is often not feasible because there is no well-defined counterfactual, or because they are so dispersed, but we quote indicative data where this is feasible. We also find that, from an economics perspective, some substantial issues are best understood not in terms of monetised costs, but in terms of other factors, especially the complex corporate and individual incentives underlying nuclear safety regulation.
10. The NERA team has been assisted in this work by the very open policy of ONR towards publication and the high quality of the extensive material provided. We have also been greatly assisted by the many individuals who have given their time to contribute to this study – in ONR, in bodies subject to their safety regulation, and in other public sector bodies with whom ONR interacts. The HSE economists have been especially helpful, in explaining HSE practices and helping with establishing contacts within HSE.
11. Chapter 2 below presents context. Chapter 3 presents our analysis of the evidence gathered from our discussions of ONR activities. Chapter 4 reviews the incentive structures faced by and within ONR and ONR's general philosophy and principles. Chapter 5 draws conclusions.

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2. Setting the context

12. This chapter sets the context of ONR safety regulation, in several dimensions. First we outline successive central government 'better regulation' policies, which focus on reducing regulatory burdens. This is followed by an outline of ONR history and its current programme structure. We then turn to the case for a strong nuclear safety regime. This is followed in turn by a wider, qualitative discussion of the costs and benefits of ONR regulation, to the industry and the wider economy, and of the extent to which these can be measured. We finally address ONR's philosophy and methodology, with its roots in the history of the HSE.

2.1. Government Better Regulation policies

13. Government Better Regulation policies have for many years focused on procedures to reduce the burden of regulation on business, especially SMEs. The instruments used include central guidance and mandatory requirements on departments and on individual regulators.[4]

14. One requirement currently for ONR is that of Impact Assessments (IAs) for new or modified statutory regulations. Such IAs for the HSE and other regulators are normally submitted to the Regulatory Policy Committee (RPC) and better regulation staff in BEIS(BIS)[5] for scrutiny. We understand that those for the ONR go via the BEIS(DECC) Better Regulation Unit. There is currently a fast track route for changes that are merely incorporating EC directives, and in ONR there have been few other changes. Where significant economic modelling is needed, as with the change to charging Applicants for the regulatory approval of transport packages, the analysis is contracted out to the HSE economists. BEIS(BIS) advise us that HSE IAs are always very good.

15. A recent new requirement arises from the Business Impact Target (BIT) regime. This already applies to some regulators, but will extend further to ONR (and many other regulators) as soon as secondary legislation is passed, perhaps late in 2016. Under this regime the business impact of all changes to policy or guidance that affect the industry, including, in the case of ONR, changes to SAPs, TIGs and TAGs, must be formally assessed and submitted to the RPC. We are told that it is designed to incentivise regulators to give greater consideration to those they regulate, and to regard them as customers.

16. The guidance most relevant to this current study of economic impact is the Growth Duty (BEIS, 2016), originally issued in 2014 and then in 2016, but still in draft form following a public Consultation.

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[4] The most relevant current general guidance documents are the Regulators' Code BIS (2014) and the Better Regulation Framework Manual (BIS, 2015). One of the best known mandatory rules is that of One [regulation]-In, One-Out, which was changed to One-In, Two-Out and now to One-In, Three-Out. This applies formally to government departments, not individual regulators, although we are advised by ONR that pressure can be placed on regulators to meet it.

[5] The merging of the previous Departments BIS and DECC into BEIS in July 2016 lost a presentationally convenient distinction between the two largely different areas of government. In this report we use the terms BEIS(BIS) and BEIS(DECC) where the relevant branch of the new Department is not immediately clear.

17. ONR stresses its compliance with the Regulators Code.[6] It has questioned the value of such a regime for its particular safety regulation role, but has nonetheless implemented a process to assess BIT.

2.2. ONR history and current programme structure

18. This section includes an outline of ONR history because, in the view of those to whom we have spoken with long experience of the industry, it is important to understanding the dynamics over time of nuclear safety regulation. We share this view, finding that the history has helped us to understand features of the current regime and helped also in thinking about challenges for the future – such as those of sustaining advances that have been achieved in very recent years.

19. ONR was established in the wake of the Nuclear White Paper of 2008 and the subsequent Stone Review (Stone, 2008), which was based on "work with the regulators to explore ways of enhancing their efficiency in dealing with the challenges of a nuclear new build programme". That Review's carefully worded recommendations pointed to radical changes in direction.

20. After much due process this led in April 2011 to the restructuring of HSE Nuclear Directorate, which included the Nuclear Installations Inspectorate as the nuclear safety regulator, into ONR as an HSE Agency. Towards the end of the same year ONR absorbed the Radioactive Materials Transport (RMT) regulatory team and its responsibilities from the Department for Transport. The Energy Act 2013 was then used as a vehicle to establish ONR as an independent public corporation from April 2014. Subsequent top of the office changes have included a new Chief Nuclear Inspector from November 2015 (confirmed in March 2016) and a new CEO from January 2016. The main programme structure has also been recently revised and there have been other very significant changes.

21. One obvious driver of change has been the emergence of the prospect of new nuclear build with the associated GDA and new nuclear construction regulatory processes. Less publicly conspicuous but also with important economic consequences was recognition, by the NDA, DECC and other parties, that the balance of high cost and slow progress in the ongoing Sellafield programme was unsustainable.

22. The nuclear regulatory scene has thus changed greatly in recent years. The progress achieved in some areas is very recent and so its long term sustainability has yet to be demonstrated. And in some areas the "first time" experiences of major new regimes may still reveal much scope for future development.

23. ONR's operational work was throughout most of this study structured under six "Key operational programmes", described by ONR as follows:

- Sellafield, Decommissioning, Fuel and Waste;
- Operating facilities;

[6] ONR(2015) 'Compliance with the Regulators' Code 2015' http://news.onr.org.uk/wp-content/uploads/2015/09/report.pdf

- New reactors;
- Cross ONR;
- Civil nuclear security;
- Assurance, Policy and International Directorate.

24. Some of these fall outside or only partly within the scope of this current study. As noted above, civil nuclear security is outside our scope. The Assurance, Policy and International Directorate's responsibilities include regulatory research, and it is therefore funding and managing this project. Although most of this Report's analysis addresses that Directorate's interests, our review does not extend to study of the Directorate itself. The one Cross ONR activity materially relevant to this study is RMT.

25. The safety regulatory staff structure to cover these programmes and their several sub-programmes is in a matrix form. A site licensee, or other regulated body, will see a dedicated ONR team, but that team will be supported, on a case by case basis, by other inspectors from teams of specialists that cover all programmes.[7]

2.3. The general case for strong nuclear regulation

26. It is widely accepted that free markets tend to maximise the social benefits obtained from given resources, but there are several ways in which the free market mechanism can fail to do this. One of the simplest types of failure is the presence of 'externalities' – that is when impacts of a market activity on social welfare are not well reflected in costs or benefits to those undertaking the activity that imposes the impact. Many health and safety impacts are of this kind. The direct financial impacts on an enterprise of deaths, injuries, or illnesses caused by the enterprise's actions (or failure to act) may fall far short of any reasonable monetary valuation by society of the harm that that they have caused. The enterprise may also be breaching society's ethical standards more generally. All developed countries therefore have extensive health and safety regulation, with bodies such as the UK Health and Safety Executive and ONR enforcing standards established by law.

27. For businesses with conspicuous major hazards,[8] a major accident, or even a single fatality, may have serious reputational and direct financial costs, perhaps especially in the case of nuclear power. It could be argued that these private costs may provide market participants with sufficient incentives to ensure safe practices, perhaps with only light regulatory inspection. But this is belied by practical experience.

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[7] Except, at present, RMT, which has its own matrix structure, although we understand that this function is soon to be almost wholly integrated into the other ONR operational programmes.

[8] The current report follows the long established HSE and ONR definitions of 'hazard' and 'risk': "*Hazard and risk are used interchangeably in everyday vocabulary. Nevertheless, it has proved useful to HSE to make a conceptual distinction between a 'hazard' and a 'risk' by describing a hazard as the potential for harm arising from an intrinsic property or disposition of something to cause detriment, and risk as the chance that someone or something that is valued will be adversely affected in a stipulated way by the hazard."* (HSE, 2001a).

28. The worst UK industrial accident in recent years was the Piper Alpha oil production platform explosion and fire of 1988.[9] The most recent major industrial accident in the UK at the time of writing was the Buncefield oil storage depot series of explosions and major fires in 2005.

29. The UK Piper Alpha disaster led to a 13-month public inquiry with many recommendations. One of the most prominent was that safety regulation for such facilities should be strengthened and moved from the Department of Energy to the Health and Safety Executive. The Energy Minister, presenting the report to Parliament, noted that the inquiry Chairmen had "made it quite clear that it would be unfair to blame the inspector involved, who had done a competent job within the existing framework" (Hansard, 1990). The failure had been with the regulatory framework, which had been too light.

30. The Buncefield explosions and fires occurred because of the massive overfilling of a large petrol storage tank, one major factor being an incorrectly installed, inoperative overfill switch. The major independent inquiry commented that "For the regulators, an accident on the scale of Buncefield is an opportunity to make changes that may previously have been inhibited for resource and other related reasons. We are therefore particularly pleased that the Competent Authority has set up a comprehensive programme for reviewing the COMAH regime."[10] That review was started in 2008 and implemented in 2010 (HSE, 2010b).

31. The three major world nuclear reactor accidents in the past half century have been Three Mile Island (1979), Chernobyl (1986) and Fukushima (2011):

    - At Chernobyl (the only one of these nuclear accidents with clear fatal consequences) there was no safety regulation, nor operator safety culture, as would now be recognised in Russia or Ukraine.
    - The Three Mile Island accident led mainly to a better understanding of the safety management needs of complex facilities. It also led the US NRC "to tighten and heighten its regulatory oversight" (NRC, 2014). (A further consequence was strengthening of the US anti-nuclear organisations, which still make frequent reference to this accident in their advocacy.)
    - The Fukushima tsunami led to a restructuring of Japanese nuclear regulation. This had been based largely in the Ministry of the Economy, Trade and Industry, which also promoted nuclear power. The function was transferred wholly to a new Nuclear

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[9] The appalling loss of life in this disaster was 167. It rightly remains prominent in public and political memory. This contrasts with a UK ferry disaster the previous year, with an even higher death toll, which no doubt also led to tighter regulation but rather soon faded into history. As is widely recognised, public and hence media and political perceptions of, and reactions to, different types of hazard can be much weaker or much stronger than can be explained by the objective risk and hazard alone. Nuclear hazards are close to the 'fear factor' extreme, beyond oil and gas. This is an important factor in the development of nuclear safety regulation.

[10] COMAH (Control of Major Accident Hazards) defines a specific set of regulations. ONR explain that the Competent Authority (CA) for COMAH at nuclear sites is a partnership of: ONR, the Environment Agency, the Scottish Environmental Protection Agency, and Natural Resources Wales. COMAH inspection of nuclear licensed sites is however carried out by ONR-warranted HSE COMAH inspectors. We sense some ambivalence around whether the CA at nuclear sites formally includes or excludes HSE. The HSE website records that the CA is 'represented' at such sites by ONR, while the ONR see HSE as not a member of the CA at such sites. This is a minor point, but one of several indicators that at the central office level the ONR/HSE arrangements are still evolving.

Regulation Agency in the Ministry of the Environment, with a presumption that this would lead to tighter regulation (NRA, 2013). It also led to changes in nuclear safety regulation worldwide.

32. All this experience confirms that, although major energy companies are by no means careless of safety, everyday pressures on time and resources can lead to decisions that cumulatively have an adverse safety impact. For high hazard operations, strong regulation is needed to sustain the physical and, especially, management systems at the levels needed across the industry to keep the risks of a serious accident at the low levels sought by governments, industry, and society at large.

33. This is reflected in the development of international coordination and development of nuclear regulation. An important example is the OECD Nuclear Energy Agency's Multinational Design Evaluation Programme (MDEP), which brings together 15 countries, including Canada, China, France, Russia, Japan, the UK and the US.[11] The UK is represented by ONR.

2.4. Identification of specific ONR costs and benefits

2.4.1. The costs of ONR safety regulation

34. The resource costs of ONR itself, almost all of which are charged to those whom they regulate, are well documented. But ONR regulation also imposes sometimes much higher resource and/or operational costs on regulated parties.

35. In public debate, estimates of "the cost of regulation" in aggregate terms are sometimes presented for, say, the cost to SMEs, or to the economy as a whole, of some particular regime or regimes. But, from an analytical perspective there is rarely, for a major regime, a meaningful counterfactual against which to measure such costs. And even if such a baseline were accepted it would rarely if ever be possible to distinguish usefully between regulator-generated costs that brought a proportionate safety benefit and those that did not.

36. But specific cases offer more promise. Much of this report is about indicative data on the extent to which ONR regulation achieves a proportionate balance between cost and benefit within its various programmes.[12]

2.4.2. The benefits of ONR safety regulation

37. Media and political interest in nuclear safety is mainly concerned, worldwide, with the potential for a release of (intensely radioactive) reactor fission products, reflecting the very high social, economic and political cost of such events.[13]

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11 https://www.oecd-nea.org/mdep/

12 The distinction between analysis of *incremental* costs and benefits of regulations and derivation of *aggregate* figures for "the cost of regulation" is a recurrent theme in public debate. Ministers (and the National Audit Office, with its accountancy base) tend to seek aggregate figures, rather as if regulation were similar to tax or expenditure, and such figures are published. But these absolute figures are of little if any use for the analysis of whether a regime provides good value, and no use if the benefits of the regulations are not simultaneously considered.

38. The NII commissioned studies of the monetisable costs of a nuclear accident of this kind, the most recent being known as COCO-2 (Higgins et al, 2008). That study is mainly methodological, but it includes a quantified illustration of the impact of a very severe accident at a reactor in south west England. This attributed estimated monetised impacts of £4 billion to human costs (predominantly fatalities), £8 billion to waste disposal, and £3.5 billion to production losses (mostly non-agricultural).[14] However these monetised costs do not include political and other impacts which, while not sensibly monetisable, would add further social costs. COCO-2 discusses some of these under the headings "indirect tangible losses" and "direct and indirect intangible losses". But these do not extend to issues such as national reputation, trust in industry and in regulators, and international impacts on public opinion and nuclear industry development. Many of these costs would arise even from a partial core meltdown that did not lead to fatalities or any substantial release of radioactive material.

39. Maintaining the probability of a major nuclear accident at extremely low levels is therefore an important social economic benefit. ONR's contribution to this, and to the confidence which it gives to government, the public and the industry, are very important contributions to national welfare.

40. These are not however contributions that can be meaningfully valued in monetary terms, for several reasons. One reason is that many factors, such as public and political confidence, do not lend themselves to simple monetary valuation. Another is that very serious major hazard accidents are so rare that there is no sensible data base for estimating the extent to which a regulatory change would affect the incidence of such events. Another reason is that any assumed counterfactual (i.e. the alternative regulatory structure against which the current structure is compared) risks being arbitrary. To assume no special nuclear safety regulation, or some form of lighter regulation, would require arbitrary assumptions: a) to define that alternative regulatory regime; b) about how the industry would respond to it; and c) about how this would affect safety performance and public confidence. Quantitative valuation of ONR's impact on the basis of such arbitrary assumptions would have little merit, if any.

41. Our approach is therefore, as mentioned above, to consider ONR's individual activities alongside plausible alternatives, under two broad and sometimes overlapping categories:

    i. Administrative efficiency: Are decisions made consistently, clearly and without excessive delay; is sufficient guidance provided on regulatory requirements and how ONR operates; is the level of intervention expected by ONR of inspectors sometimes unduly heavy, or unduly light?

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[13] This is not to dismiss the long running debate on nuclear waste disposal. But the political debate in the UK appears to have eased since environmental groups came to agree that deep storage was the least bad long term solution. The issue is important to some ongoing ONR decision making, but we do not consider it further in this study.

[14] The sum of these costs was equal to 1% of UK GDP in 2008. HSE have commissioned a study using a similar methodology for non-nuclear accidents, but extending over a wide range of mainly less severe cases (Health and Safety Laboratory, 2015). The 'economic' costs of the Buncefield accident were estimated to be £0.9 billion, of which 70% was compensation costs and the rest nearly all financial costs to the aviation industry (MIIB, 2008, para 72). The study identifies other costs, such as closure of the M1, M10 and M25 motorways, that were "unquantified". As there were no serious injuries and the technology was relatively simple, the political and reputational impact of Buncefield, given vigorous action to 'do better in future', may have been very limited.

ii. Technical and professional standards and conventions: Are inspectorate decisions always made on the basis of fully appropriate qualifications, training and experience? How well do the institutional criteria for assessing costs against changes in risk (especially very small changes) in principle optimise social welfare? And how are they applied in practice?

2.5. ONR philosophy and methodology

42. ONR and the HSE have over time developed some conventions that are distinctive to their respective responsibilities. However ONR shares with the current HSE the same history (notably including TOR and R2P2, and ALARP/SFAIRP) and in most areas the two regulators follow the same underlying philosophy.

43. The philosophy is based on the principle of non-prescriptive regulation, with the onus placed on the employer/operator to achieve certain goals, as opposed to being required to follow technically detailed regulations. This contrasts with many other countries, where safety regulation is based much more on prescriptive rules and conventions. Whether for this or other reasons the general performance of the UK as a whole in terms of workplace fatalities (the most reliable international comparative metric) has for many years been impressive.[15]

44. Another, crucial dimension of regulation is the culture within which the regime is implemented. The enabling regulation initiative (see Appendix A) now promoted by ONR top management encourages a 'cooperative' approach. This entails good understanding of the interests of the body being regulated, albeit with the firm avoidance of any element of, or any behaviour that might be interpreted as indicating regulatory capture. The enabling regulation initiative is widely welcomed across the industry, although views differ on its breadth, and the general message is applied in some programmes and by some inspectors more than others.

45. TOR and R2P2, and ONR and HSE guidance on SFAIRP/ALARP, set out the regulators' approach to risk, and are therefore concerned with (among other things) the balancing of costs and benefits, which is fundamental to "economic impact". TOR, developed by the HSE in the course of the Sizewell B Inquiry, was a seminal work. Drawing on ethical considerations, it distinguished more clearly than ever before between "upper tolerability limits" – beyond which people should not be exposed to fatality risks, irrespective of costs, except in wholly exceptional cases[16] – and cases where increases in risk should be set against any associated change in cost (including costs which cannot be monetised).[17]

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[15] "The UK consistently has one of the lowest rates of fatal workplace injury across the EU. In 2012 the standardised rate was 0.58 per 100,000 workers, which compares favourably with large economies such as France (2.64 per 100,000 workers), Germany (0.9 per 100,000 workers), Italy (1.29 per 100,000 workers) and Spain (1.99 per 100,000 workers) (Eurostat, European Statistics on Accidents at work, 2012)." (HSE, 2015)

[16] It is however noteworthy that today's internationally accepted ICRP nuclear workplace upper limits are set at levels which, though perfectly reasonable, probably present only a very low health hazard. This fairly precautionary approach differs from the R2P2 upper limit concept of fatality risks for workers of 10^{-3}.

[17] The lower limit, beyond which further cost-effective risk reduction is still desirable but need not be actively pursued, is less significant. However there is here a curious difference between UK and US convention. In the US, the guidelines of the Nuclear Regulatory Commission appear to *explicitly preclude* any encouragement of expenditure to reduce risks below specified lower limits: http://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0058/br0058r4.pdf.

46. The main criterion applied to 'tolerable' risks is that they be reduced to levels that are ALARP, which in legislation is described as SFAIRP. HSE and ONR guidance documents on how ALARP is to be determined explain that "relevant good practice" (RGP) provides the benchmark for most applications.[18] Sometimes there is no RGP, in which case the normal procedure is to apply professional judgment, supported by relevant analysis. ONR generally leaves it open to the duty holder to submit a formal cost benefit analysis to help inform such judgments, but in practice this appears to be extremely rare.[19] To fully capture the wider economic impacts of safety measures, such assessments would in any case need to reflect in some way public and political perceptions of risk, particularly where realisation of a hazard may have wide socio-political consequences.[20]

47. The relevant ONR TAG (ONR, 2017) explains in paragraph 5.4(7) that "The ALARP case should be fit for purpose. If the risks are high then the demonstration of ALARP needs to be more rigorous than if the risks are low. The degree of rigour should also depend on the consequence level. For higher consequence situations the consequences should weigh more heavily than the frequency estimates. Furthermore, thought should be given to the robustness of the conclusions with respect to uncertainties and to any assumptions employed in the demonstration." In the next subsection it explains that: "If the ALARP demonstration employs a comparison of costs and risk-reduction benefits to rule out an improvement, it must be shown that the costs (sacrifice) of the improvement would be 'grossly disproportionate'."[21]

48. This definition of ALARP is deeply embedded in ONR and widely disseminated, for example in SAPs (ONR, 2014) and the General Inspection Guide (ONR 2016a). Its literal insistence upon spending on safety up to a point of gross disproportion does affect regulatory decision making in some, though not all ONR programmes. ONR's position is that this is consistent with – and indeed, required by – the HSWA and applied across all activities regulated by, for example, the HSE. We discuss these issues in more detail in section 4.2, below.

49. At the same time a key principle of enabling regulation is that: "We need to keep focussed on the outcome we are trying to achieve, considering all relevant factors and

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[18] Relevant good practice will inevitably take into account the practicability of a particular safety measure, so it will already reflect some balancing of costs and benefits, albeit not the more formalised approach used for cost benefit analysis. We presume that relevant good practice, where it has evolved over years in cost-conscious environments, is at least nearly always cost effective in the sense that costs will be as low as possible to achieve the relevant standards. Whether it is also economically *efficient* depends on whether the standards themselves are set at levels proportionate to the costs that they impose. These are related, but distinct, questions.

[19] Despite much questioning we have discovered only one such case, and in that case its influence appears to have been *de minimis*. We have been unable to establish whether any CBA was presented to the Sizewell B Inquiry, at which HSE did however recommend the use of the disproportion factors cited in the next paragraph.

[20] It has been suggested to us from within ONR that such wide issues should be outside the scope of ALARP. But they are relevant to a hazard's potential economic impact, broadly defined. We return to this in section 4.2.2.

[21] It sets out various gross disproportion factors ranging from 2, for low risks to the public, to 10, for high risks to the public. In practice these factors appear to be virtually never used in the nuclear context, since radiation dose impacts are never monetised. ONR (and HSE) also emphasize that there is no "algorithm" that can be used to make these assessments, and that they require informed judgment.

acting proportionately."[22] We discuss the tensions between the emphasis on proportionality and the implied insistence on *disproportion* in section 4.2.

3. Review of ONR activities

50. This chapter draws on documentary sources and our discussions with ONR inspectors, site licensees, GDA RPs, Transport applicants, and public sector bodies to develop a picture of ONR's economic impact. Section 3.1 discusses our findings on ONR's operational programmes. Section 3.2 discusses ONR's interfaces with other public bodies. Sections 3.3 and 3.4, after a historical overview, address comparisons with other regulatory regimes.

3.1. Operational programmes

51. This section summarises our findings on each of the programmes that we studied. In each case we broadly cover the background, any special features of the regulatory philosophy/approach, its apparent cost effectiveness and then other relevant material.

52. All the inspectors we met were experienced and had general, rather than specialist, technical assessment responsibilities. Common features across all individuals and programmes, which we do not generally repeat below, were: a strong awareness that their task is one of law enforcement; close familiarity with SAPs and relevant TIGs and TAGs, including the guidance on ALARP; and routine emphasis on relevant good practice as a criterion for approval.

53. The licensees and other regulated parties whom we met or spoke to were all senior staff with long experience in the nuclear industry.

3.1.1. Sellafield

54. Sellafield, with its wide range of facilities and its high hazard legacy ponds and silos, is a case study in how a particular attitude towards safety regulation can have a negative economic impact and in how, with much effort, this can be transformed. It also serves, and is widely used as an advertisement for the principles of enabling regulation.

55. For many years leading up to the creation of ONR in 2011, progress in decommissioning at Sellafield was unsatisfactory, given the resources allocated to it. And it was recognised that one factor was the somewhat rigid, compliance-based safety regulation ethic that had developed, discouraging fresh thinking among inspectors and operating staff.

56. A major reform was developed by ONR. This restructured the regulation, with separate sub-programmes for the standard inspection roles and decommissioning of the high risk facilities. It established a permanent G6 structure, bringing together all the main institutions in a high level forum, meeting on site at Sellafield, hosted by Sellafield Ltd, and an "engine room" with a continuing series of working groups, chaired at

[22] Another key principle deplores "the sub-optimal use of scarce resource", but this is in the context (with Sellafield presumably in mind) of discouraging *dutyholders* if they propose such actions.

Superintending Inspector level.[23] It also established a new ethic, finding a balance that enabled cooperative working with the licensee towards a common goal, while retaining the inspectors' independent and proactive role as safety regulators. One factor considered necessary to achieve such a radical change of ethos sufficiently quickly was a large-scale change of inspectorate staff.

57. In any effective safety regime for a large and complex facility there will always be problems between regulator and licensee, but there appears to be a wide acceptance that the regime is now about "as good as it gets". One consequence of the changes is that the safety regulator now perceives the licensee as needing to be drawn to a more flexible mind-set, while under the previous regime the licensee perceived the regulator as an obstacle to creative thinking. This reversal may be due in part to the fact that whereas most ONR staff changed to facilitate the introduction of the new culture, the licensee's staff did not change, so the cultural shift has been slower to appear within the licensee.

58. The current Sellafield regime is widely and in our view rightly seen as a creditable, practical example of Enabling Regulation, as defined in Appendix A and discussed in section 3.5 below.

59. The regime is strongly cost effective relative to the previous regime. We understand that the two most recent financial years have been the best ever for the performance of Sellafield Ltd.[24]

60. One respect in which Sellafield safety regulation is "simple" is the relative absence of competing pressures (which are found at operational power plants, for example) to generate revenues from business activities. The Sellafield budget, out of which ONR's costs are paid by Sellafield Ltd, is fixed by the NDA. The challenge is to make the best use of that budget to achieve the common objectives of effective risk management and reduction. Relevant good practice is widely applied. ALARP does arise, but, while higher priority is given to the "intolerable" risk facilities, we understand there is no "disproportionality" in Sellafield's budget allocations or activities. In other words, even if ONR believed that Sellafield ought to do significantly more to reduce risks – up to a point where expenditure was grossly disproportionate to the benefit achieved – this would be constrained by the fact that governments are unlikely to accept the setting of any spending agency budget at a "disproportionate" level.

61. A strategic concern of Sellafield Ltd is that the new world is still very young. The pre-reform days illustrate the default condition to which regulation may return unless the current more open and interactive style, with its well-recognised reputational risks,[25] is actively maintained in the medium and long term. This we discuss later.

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[23] The group bring together BEIS (DECC), NDA, Sellafield Ltd, the Environment Agency, SHEx (the Government's Shareholder Executive) and ONR. In the words of ONR, "All members work through a collaborative approach towards the common objective of facilitating hazard reduction, for example by enhancing opportunities or removing barriers to progress" (ONR, 2016e). This reference also lists eight "improvement themes" which are seen by Sellafield Ltd as applying also to G6. Another G6 member referred to the "G6 ethic".

[24] ONR reform has of course not been the only change. The termination the contract with Nuclear Management Partners to operate Sellafield, announced in January 2015 and completed in April 2016, with Sellafield becoming a subsidiary of NDA, should also be improving productivity. But the safety regulation reform appears to be the main factor.

[25] As stressed in the Key Principles of Enabling Regulation as recorded in Appendix A.

62. Similar, unsolicited concerns were expressed to us by other experienced figures in the industry, in relation to enabling regulation in general.

3.1.2. Nuclear transport

63. This section addresses nuclear transport – that is, the transport of radioactive material associated with the nuclear fuel cycle. Non-nuclear transport, of other radioactive sources, is addressed in section 3.3.6.

64. Radioactive transport safety regulation (nuclear and non-nuclear) applies prescriptive international standards to "packages" of radioactive materials. The issue of economic impact is therefore less significant than in other areas of nuclear regulation, where there is much more scope for judgment about what is or is not ALARP. Radioactive transport does however have some scope for discretion by the regulator and considerable scope for delivering the service more or less efficiently and effectively.

65. The Regulations allow discretion most notably with respect to "special arrangements", whereby the Competent Authority may authorise additional safety measures to compensate for a relaxation in another area, such that the overall level of safety is maintained. We are told that in this respect ONR has recently become somewhat more flexible in willingness to consider such requests.

66. As for service delivery, nuclear transport is a story, from the perspective of the regulated parties, of striking improvement from a prolonged period of difficulty, following the transfer of the function in 2011 from DfT to ONR. The difficulties appear to have stemmed almost wholly from the problems, in a period of major geographical and institutional change and uncertainty, of maintaining the staff skills and levels needed to provide a satisfactory service.

67. There is some perception within ONR that transport regulation was bad in the Department for Transport but perked up soon after its move to ONR, but the recovery, in the experience of the regulated parties, was a long haul. It appears that ONR inherited a regime from DfT in 2011 that had deteriorated seriously since the announcement of the move and was still declining. We are told that the nadir of service in nuclear transport was in 2013, and that recovery to close to previous levels was achieved only in 2016.[26] But this recovery will have been a very challenging task, which ONR appears now to have well under control.

3.1.3. Operating Facilities and Decommissioning, Fuel, and Waste

68. Operating Facilities and the sub-Programme of Decommissioning, Fuel, and Waste are here combined because, in the context of this study, they present activities with similar characteristics. They all entail fairly close and long-term professional relationships between the licensee and ONR, and involve risks and hazards which, while in some cases extremely serious, are expected to remain well under control, at far below intolerable levels.

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[26] We were told by a regulated party of an ONR, international conference presentation in 2013 that gave a good picture of UK transport regulation, but reflected aspiration that was very far from reality at that time.

69. There is nonetheless an important divide between Magnox, with its public NDA funding, and EDF-NGL and Springfields with their private commercial funding from the sale of their outputs. Unsurprisingly private sector companies are significantly more concerned about costs and the reasonableness of ONR decisions, even though they rarely if ever consider serious challenge worthwhile.

70. However responses from all these licensees report favourably on the professional and consultative quality of their senior inspectors. Some see this as "enabling regulation" in practice. Others welcome this quality but feel that it falls short of a deeper view of enabling regulation.

71. Less experienced, and a minority of, specialist inspectors in these programmes are considered to fall sometimes disappointingly below enabling regulation standards, imposing some avoidable regulatory burden.[27]

72. The post-Fukushima shut-down of one of the reactors at Dungeness B for two months, while extra flood-protection measures were installed (and while the other reactor was shut down for refuelling), is seen by the operator as an example of excessive conservatism that was not in the public interest. The operator was told that the extra protection would be required unless it could be demonstrated that the risk of such a flood was less than 10^{-5} per year – otherwise the operator would not be able to demonstrate that the risk was below the BSL threshold of intolerability. Because the raw data was not available at the time in such terms this could not be readily demonstrated. Having accepted this, the plant was formally unsafe until the measures were in place and so had to be shut down. By convention the argument that the time period in question was only very short is always inadmissible. There is sound logic here as a general rule, and good arguments for resisting exceptions to them – but there also may be reasonable arguments in support of greater flexibility in certain limited cases. [28]

73. Nonetheless, more generally, the interpretation of ALARP in these programmes appears to require little more than the application of relevant good practice, with little or no explicit reference to "disproportionality".

74. A thorough, evidence-based assessment of ONR's economic impact in these fields would need an interdisciplinary comparison with the regulation of similar facilities in other countries, to provide baselines for comparison. However, from the unavoidably limited information collected in this study, the picture is good.

75. Like Sellafield, the Magnox programme enjoys the simplicity of a publicly funded NDA budget, apparently together with a trusting relationship between licensee and regulator. This should again lead naturally to a cost-effective allocation of expenditure and activity. The main problem areas identified by the licensee are in adaptation of the Licence Conditions to the circumstances – not anticipated when the Conditions were drafted – of

[27] We are not in a position to delve into such cases, which may stem in part from personality and in part from training and experience. They do however, in our view, illustrate the need for feedback to ONR about how inspectors perform in the field against enabling regulation criteria.

[28] ONR point out that, as is normal, the shutdown decision was made by the operator, in the knowledge that ONR conventions required this. And restart was allowed after some upgrading of plant, procedures and training, but before completion of a sea wall around the site that was considered necessary to reduce the risk of flooding to a required level of less that once in 10,000 years.

a declining industry. ONR is responding to these concerns, but the licensee would like to see a more proactive, high level examination of what changes are needed in such circumstances.

76. As for the regulator's fees, ONR note that for operating reactors the US NRC appears to charge for eight times as many FTE inspectors per reactor as are charged by ONR to EDF-NGL. This is not questioned by NGL, who attribute it to the difference between prescriptive and non-prescriptive regulation. The former demands less analysis from the licensee but undertakes more by the regulator (as illustrated in Appendix CD). The ONR fees for fuel manufacture, while perhaps on a par with some other European countries, also appear to be less than in the US, by a lower but still significant factor.

77. There will be many ways in which such numerical comparisons would need to be refined to provide a reliable comparison.

3.1.4. New reactors: GDAs

78. The GDA programme is implementing a technically challenging, and politically and economically important programme, in a field in which the UK had had no experience for more than 25 years before two Requesting Parties (RPs) (EDF and Westinghouse) submitted their designs for UK reactors in 2007.

79. Our findings suggest that the GDA regime shares crucial, positive features with other ONR nuclear safety regimes. They suggest that the regime is handled by inspectors with high technical skills and specialist knowledge, a strong and conscientious commitment to their task and a close attention to detail and due process. And its primary criterion for acceptability is relevant good practice.

80. There was also a consensus among RPs that the underlying rationale for the GDA regime, i.e. to reduce the costs of regulation and licensing of new sites, is sound. And there was support for the idea that the GDA regime was likely to result in lower costs than would have been incurred without the initial approval of the high level generic design.

81. It follows that we find no reason to doubt that that the GDA regime well serves its primary objective of ensuring that any generic design that achieves a Design Acceptance Certificate meets, as a generic design, an acceptable level of safety. We are told of, and impressed by, issues that have been missed by other national regulators but then uncovered by ONR, and duly incorporated worldwide.[29]

82. The GDA regime does however face exceptional challenges in its incentive structure and its relationships with RPs. This applies, as follows, to all of the incentives listed in section 3.1 above.

    i. It faces no financial constraint. Its staffing in-year is constrained, but if an issue is found to need more time the work may continue into future years until it is

[29] We are told in this context that there is substantial exchange between nuclear regulators internationally. ONR, ASN (France) and NRC (Finland) came to agreed positions on issues for the AP1000 and the EPR during the GDA. More widely, the OECD MDEP is an important forum for harmonisation where this is practicable.

resolved.[30] Apart from the fees charged to RPs, ONR has no knowledge of the RP's resource costs, or of the reactor construction or operating costs of its requirements.

ii. The personal and institutional rewards to individuals, and the regime as a whole, are in terms of what measures can be found to reduce risk. This is of course fundamental to the regime's role. But there appears to be little check on how far it should extend to potential risks that are much less than 10^{-6} per year.

iii. Statute law and natural monopoly. We understand that statutory authority does not extend to the GDA Process. But *de facto*, when there is any sustained disagreement between a socially concerned regulator and RP experts, inspectors can and do prescribe their personal view.

iv. The "gross disproportion" convention reinforces all these incentives. RPs are reminded of this phrase, to a degree that appears to exceed that in other programmes, perhaps partly because some RPs will less familiar with GB conventions than established operators.

v. The political profile of nuclear safety and low-level public anxiety about nuclear technology is further reinforcement. This is sometimes put to RPs as a case for disproportionate requirements (although RPs may have considered this as seriously as ONR in the development of their designs).

vi. And finally the concept of enabling regulation poses special challenges for a regime that is dealing intensively with bodies that are initially unfamiliar with and unknown to the regulator. This will have given no time to build up a foundation of trust, and in a role that is inherently more confrontational than in any other operational programme. The one example we have seen in this programme of the spirit of enabling regulation is that, following the report (Environment Agency and ONR, 2013) on lessons learned from the early GDAs, it does appear that the recommendation that more should be done to bridge cultural barriers with RPs has been acted upon.

83. These six incentives describe the world as it is, but the impact of the first five depends in part upon the regulatory culture adopted by the particular regime. An aspect of the GDA regime that may be striking to any outside observer with experience of risk analysis is the strong policy of excluding any knowledge of costs (other than fees charged to RPs). It is inevitable that the outcome will be excessive costs. Quantification of how much this is likely to cost would however require a study by nuclear experts on a par with those in ONR and the industry.

84. Given this ONR approach to costs, the responses of RPs do not surprise us. RPs might be expected to say that they are disappointed that UK requirements are more severe than those of other countries, and that in specific cases they thought ONR requirements had

[30] ONR has incentives to ensure that *its own* responses to the RP's submissions are timely, but it may then require further RP analysis or modifications. We understand however that ONR does set a maximum for its own fees for a GDA – and that this maximum tends to be met.

been at least debateable. But the strongest RP concern is that a procedure that claims to be non-prescriptive has become prescriptive in practice, with rules that depend upon the experience, interests and personal opinions of the individual inspector, and perhaps on choice of institutional culture.

85. One experienced licensee, from another field, commented to us that "goal-setting" can be superior to prescriptive regulation so long as a "good dialogue" gets underway between the regulator and the regulated entities: otherwise, hard-and-fast rules may be better. An RP described the prescriptive approach in other countries leading to "a relationship with the regulator in a [shared] design journey", which the current UK process appears not to achieve.

3.1.5. New reactors: New nuclear construction

3.1.5.1. The new reactor construction programme

86. This programme, established to work on the site specific licencing of a reactor that has achieved generic design acceptance, is of course a new programme. And it is currently dealing with only one licensee, with the process still at a very early stage. We have therefore not discussed the programme itself in any depth with ONR.

87. The discussion did however range more widely and provided important contributions to the project in three respects. It provided further background on the GDA process, in which the new construction licensee had been closely involved. It introduced us to a contact elsewhere in ONR who provided invaluable advice on methodology. And it raised the matter of the EPR Filtered Containment Vent (FCV), as discussed below, which was carried over at the end of the GDA as an issue still to be resolved.

88. The licensee's comments in the new construction licensing process, apart from the FCV, included two main concerns.

89. One was concern about the considerable costs that are likely to arise from design changes at this stage, as construction starts. It was stressed that the impact was not only on capital costs, but also on scheduling, with delays incurring potentially very high costs in financing and loss of output. They wished to ensure that such costs are given their due weight.

90. The other was a more specific concern about whether the construction assessment process was proportionate all of the time. It currently entailed some three hundred meetings per year, of typically 10 people at each, involving much travel as well as meeting time and preparation. They recognised the licencing responsibilities of ONR and the focus on early design and organisational capability in a new project, but thought that more could be done to rely on internal company governance and review and assurance processes.[31]

[31] The licensee's current perception is clearly that the current process is excessive. Another source has however mentioned to us that the licensee has also been concerned to avoid delays arising from ONR not having the information needed to for the construction to progress to schedule, and that this may explain the scale of the interactions.

3.1.5.2. The EPR filtered containment vent (FCV)

91. The Fukushima incident in March 2011 changed perceptions of relevant good practice to limit containment pressure in the event of a severe accident. NNB was therefore required, relatively late in the GDA process, to demonstrate to ONR's satisfaction that consistency with relevant good practice did *not* require the installation of FCV technology. The issue was not resolved for three years.[32]

92. ONR inspectors helpfully referred us to the issue as an example of a cost benefit analysis (CBA) being assessed by ONR as a part of its decision making process. However as noted earlier, this proved to be the only CBA that we have been able to find, despite persistent questioning. It also emerged on closer study that, in this FCV ALARP case, the CBA was not an important element.

93. More important in this case than the use (or otherwise) of CBA, is the very substantial time and cost entailed in resolving the issue. We understand that, from the time of NNB's submission of the safety case, ONR's assessment took about three months, which is a normal length of time for such an assessment. But NNB felt that the preceding years which led up to the assessment were not normal. The sensitivities surrounding these years are such that we can record no more than a superficial view, but we were advised that the costs to NNB (if not to ONR), were very substantial. We understand that NNB faced the task of "proving the negative" that they had not missed anything, using extensive probabilistic safety analyses. This included analysis to demonstrate that the annual probability of certain sequences of events was of 10^{-9} or 10^{-10} per year, which NNB considered excessive. We understand that some ONR specialist inspectors were adamant to the end that the vent was needed. We believe that high-level management time was also addressed to whether ONR would close the issue with a public requirement that the vent should be installed.

94. It has been suggested to us by an experienced, front line inspector that, as the FCV became a major issue, it had perhaps been taken as an individual issue out of context, without the opportunity for the licensee to present the wider safety case position. When the overall safety risk position was reviewed and the impact of FCV was considered, the arguments became clearer.

95. The case suggests that the existing mechanisms for escalating such issues were not as effective as they could be. It implies the need for better mechanisms to resolve technical disagreements between ONR and industry experts that cannot be resolved at working level.

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[32] The challenge was recorded by ONR as follows: "NNB GenCo has decided to ensure that an option for fitting Filtered Containment Ventilation (FCV) including the relevant penetrations through the Airplane Crash (APC) shell and containment is retained by installing blanked pipework through the containment/APC shell and by allocating space for a FCV filter system. However, NNB Genco's position is that FCV is not required in the EPR design and the project intent is to maintain the design without it. ONR does not consider that it has been demonstrated that FCV is not required in the UK EPR design and this was made clear to NNB GenCo. Consequently NNB GenCo accepted an action to provide a plan/strategy for the production of a safety case for the control of containment over pressurisation in the UK EPR (ONR, 2013).

3.1.6. Non-nuclear transport

96. We noted in section 3.1.2. that nuclear transport is a story of striking improvement from a prolonged period of difficulty. However for non-nuclear transport, although the same regulations are enforced by the same Radioactive Materials Transport (RMT) team, the feedback we have from (a small sample of) SMEs that depend on RMT's services is less upbeat. The mandatory international standards are not controversial. And the quality and attitudes of more senior RMT staff are praised. But the quality of some front line staff in this sub-sub-programme appears to be a source of frustration.

97. A separate issue, which may or may not be a matter for government concern, is that the ONR fees required for the licencing of package design assessments in this sector appear to be too high for at least some SMEs to continue to undertake such work.

98. The reported long-term dissatisfaction with front-line staff did not at the time appear to be well known within ONR.[33]

3.2. Interactions with other administrative bodies

3.2.1. Department of Business, Energy and Industrial Strategy

99. The closest interaction of BEIS(DECC) with ONR is in its involvement in Sellafield. BEIS sits on several sub groups of the G6 engine room, which is chaired by ONR. The department strongly welcomes the Sellafield regulatory reforms and refers to the "G6 ethic" of cooperation.

100. Formal government responsibilities for ONR are spread across BEIS(DECC) and DWP. DWP is accountable to Parliament for the overall governance of ONR, the effective use of its resources, and for conventional health and safety at nuclear sites. BEIS(DECC) is accountable for the development and effective delivery of UK civil nuclear regulatory framework and policies. The two Departments thus have a common responsibility in ensuring the effective and efficient regulation of the nuclear industry.

101. ONR regulatory decisions are independent from Government. Thus, except on some ongoing issues in the special context of Sellafield, BEIS(DECC) responsibilities do not extend to assessing the cost effectiveness of ONR operational decision-making criteria, beyond supporting the broad principles of goal setting regulation and ALARP, and pressing for consistency. DWP's interests are still more remote from operational issues.

102. BEIS(BIS) sets better regulation requirements such as the BIT, the Regulators' Code and the Growth Duty but, apart from its examination of IAs and proposed changes under the BIT regime, it has no operational role in how regulatory staff apply regulations.

[33] ONR tell us however that stakeholder engagement in November 2017 (some 18 months after our primary research was undertaken) was very positive on front line staff.

3.2.2. The Environment Agency

103. The Environment Agency Nuclear Regulation Group, ONR, and licensees all described the working relationship between the Agency and ONR as good. We understand that the Memorandum of Understanding between the two regulators was updated in 2015.

104. The Agency chose for this study to present an entirely positive picture of the relationship, apart from a passing reference to historic issues, now resolved, in relation to high level waste. Issues mentioned to us by others do not appear to suggest potential for improvement in the general working relationship.

105. The Agency also explained that they have adopted an "enabling" approach for many years, enshrined in their Corporate Plan as "Take a 'yes if' approach in all we do."[34]

3.2.3. The Nuclear Decommissioning Agency

106. The NDA reported an extremely high regard for ONR's implementation of its enforcement role, in which the NDA did not seek to interfere.

107. It noted that the NDA was much freer to talk with ONR and the Environment Agency on challenges to the regulatory approach than were the operators, and there were discussions of such strategic decision making, both formal and informal. One area within which issues arose was the question of when the ONR regime was no longer needed, or the question of at what point does ALARP not need to be applied? (The NDA does not need to demonstrate that its strategic decisions are ALARP/BAT/BPEO, but the operators have to demonstrate that their implementation of the strategy is.) Such end of life regulation at present potentially incurs a very high financial cost relative to the safety benefits.

108. Although the engagement on these issues is good and getting better, NDA felt there was scope for development in ONR's wider strategic approach to such issues.

109. NDA were also concerned about the potential unhelpful feedback between public fear of low levels of radiation and regulatory behaviour, which may place undue weight on reducing risks of very low-level exposure.

3.2.4. The Health and Safety Executive

110. ONR shares with HSE and the environmental agencies the Competent Authority role for COMAH. It issues ONR warrants to HSE COMAH inspectors for COMAH sites. At the site level this appears to be free from significant problems. There is evidence of transitional issues for a regime that is still in its early days. These have not however affected relationships between regulators and licensees. Overall the system appears from this brief review to working satisfactorily.

111. We understand there is a similar regime for construction inspection, but we have not enquired further about this.

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[34] It is interesting to set this against a guide by the nuclear industry, which sets out the ONR guidance very fully and notes that the ALARP process is "a 'Why shouldn't it be done approach' rather than a 'Why should it be done?' approach" (IRPCG, 2012).

112. ONR has also employed HSE economists to produce regulatory Impact Assessments. This has proceeded smoothly, but the need has not arisen since it was established that HSE will charge for such services.

3.3. Comparisons with other major hazards

113. This section first places nuclear energy in the historical context of other major hazards. It then looks at HSE offshore regulation as a non-nuclear example of safety regulation of a large international energy industry major hazard activity.

3.3.1. Historical overview

114. UK major hazard safety regulatory regimes have slowly evolved over half a century.[35] The Windscale fire in 1957 led to the Nuclear Installations Act, 1959 and formation of the Nuclear Installations Inspectorate. The Flixborough chemical explosion of 1974, followed by the Seveso disaster in Italy in 1976, led to the 1982 EC Seveso Directive (influenced largely by the HSE) and hence to the HSE COMAH regulations in 1984. The Piper Alpha North Sea disaster in 1988 led to the transfer of offshore regulation to the HSE.

115. The Three Mile Island nuclear meltdown in 1979 led to major changes in the regulation of nuclear safety management and design.[36] The Southall and Ladbroke Grove railway accidents of 1997 and 1999 led to changes in the regimes for setting railway standards and accident investigation, and Inquiry criticisms of the Inspectorate included that of "too much trust in the duty holders". The Texas City refinery explosion of 2005 had implications for HSE's regulation across many major hazard sectors, as did the Buncefield explosions and fires later in 2005 for its regulation of that industry.

116. The Fukushima nuclear meltdowns in Japan in 2011 led to a major reassignment of responsibility for regulation of the industry in that country, and to regulatory modifications worldwide. It also tipped politics in Germany to a planned termination of the country's nuclear power programme: an illustration of the potential for serious nuclear accidents, even if they may cause no immediate deaths or serious injuries, to have extreme political and economic consequences.

117. For major hazard industries generally, safety regulation responds to rare events that often *appear*, with hindsight, to have been foreseeable by a well informed and open minded manager or regulator. Some cases may perhaps have been foreseen by some staff as plausible, but left untouched or unmentioned because of cultural inertia.[37]

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[35] These cases are taken mostly from HSE sources: http://www.hse.gov.uk/news/buncefield/major-hazard-incidents.htm; http://www.hse.gov.uk/aboutus/timeline/

[36] The NRC (2014) lists twelve such 'major changes' in US regulation as a consequence of Three Mile Island.

[37] HSE record that, in the case of Buncefield "the Judge … commented that cost cutting per se was not put forward as a major feature of the prosecution case, but the failings had more to do with slackness, inefficiency and a more-or-less complacent approach to matters of safety" (HSE, 2005). We cannot speak with authority on the nuclear cases, but to the best of our understanding Windscale was then part of the defence programme and cost saving was not an issue; Three Mile Island revealed human and technical complexities that were understandably not foreseen; and Fukushima reflected inadequate industrial and regulatory standards in the 1970s that, perhaps through cultural inertia, subsequent regimes left unquestioned.

3.3.2. HSE Offshore and nuclear safety regulation

118. HSE major hazards and ONR share many fundamental concepts, notably the Health & Safety at Work etc. Act, 1974, and hence ALARP/SFAIRP and TOR (which was developed in the context of Sizewell B, and formally broadened to other sectors in 2001 in R2P2). In both regimes 'Dutyholders' have the primary responsibility for the ongoing management of major accident hazards associated with their operations. Offshore (consistently with ONR) this will be the 'Installation Operator'.

119. Offshore and nuclear differ greatly in their technologies and associated hazards. Offshore there are a number of major hazards, including fire and explosion, structural collapse and a ditching helicopter, but limited safety hazards on land. The major hazard of either a loss of core cooling with a slow heating to fuel meltdown, or an accident with spent fuel or its by-products, perhaps from very old legacies, are potential hazards to the general population. Both technologies are complex but nuclear power may be more complex in potential paths to a serious failure.

3.3.2.1. Political contexts

120. The costs of a serious offshore accident can be financially massive. Deepwater Horizon in 2010 cost BP, including compensation costs and penalties, well over $60 billion. In UK waters in 2012 it took 51 days to successfully "kill" a well after a major gas leak, with an estimated cost of around £1.4 billion in lost revenues and £0.25 billion in costs of dealing with the incident. However even an accident as dreadful as Piper Alpha did not threaten to terminate all offshore production and the global consequences of such an accident might be significant, but not existential.

121. Fukushima, in contrast, has had major international impacts on the political acceptability of nuclear power. A major release of nuclear fission products, as noted earlier, might also lead to massive social costs in terms of fatalities, long-term illness, lost production, and the costs of long-term clean up.

3.3.2.2. Regulatory structure and processes

122. The technological, locational and institutional differences between offshore and nuclear regulation lead to significant differences between the regimes. ONR is much more free standing than the HSE offshore regulator. There is also, despite the decommissioning of rigs, little if any analogue in offshore safety regulation to the regulation over many decades of nuclear decommissioning sites, with their publicly funded joint endeavours to eliminate existing hazards as soon as is possible, safely and within the available budget.

123. However there are some rather weak analogies with the processes of approving new facilities and regulating their operation.

124. To obtain a licence to drill, the prospective Licensee is required to submit a capability submission to the Oil and Gas Authority. HSE and BEIS acting in partnership as part of the Offshore Competent Authority (OSDR) are consultees in this licensing process where health, safety and environmental aspects are reviewed against specific criteria. OSDR comment is then considered in conjunction with wider concerns such as financial capability and exploitation strategy and from this point a license may be awarded.

125. Once a licence has been granted the licensee may decide to appoint a person to act as Operator on its behalf.[38] Installation Owners or Operators are the Dutyholder, who (consistently with ONR regulation) assume primary responsibility for the ongoing management of major accident hazards associated with their operations – not the licensee.

126. Operators of new UKCS production installations are required to send a design notification to the Competent Authority. It is common for the Dutyholder to meet with Regulatory Specialist Inspectors to discuss design aspects in detail to ensure any barriers to compliance are identified at an early stage. The Dutyholder then has to consider the comments of the Competent Authority at this stage, but is not legally obliged to act on them. The Dutyholder (operator or owner) will then develop a safety case for acceptance by the Competent Authority before operations commence.

127. The design stage for an offshore installation, particularly a novel design, can take years. However the HSE assessment period for new safety case assessment is **six months** for production installations and **three months** for non-production installations. There is however no close analogue to a new reactor design, perhaps from an unfamiliar supplier, with multiple and complex range of failure and failure response modes, mostly very different in character from those of an oil or gas facility.

128. Once the offshore safety case has been accepted, other activities will require further notification to the Competent Authority, such as combined operations (work between two or more installations) or well development. Submissions are reviewed by the Competent Authority and work cannot commence if the Competent Authority objects to their content.

129. The Dutyholder must review the safety case every 5 years. It is also stressed that the safety case is a working document made available to personnel in an accessible manner, with the workforce consulted on its content.

130. The organisational arrangements for the inspection of offshore facilities and nuclear sites have features in common. HSE Offshore Inspection Management Teams (IMTs) are given responsibility for particular companies and (as in ONR) Topic Specialists work across industry as required. Each Dutyholder is assigned an IMT Inspector. Usually, each IMT will have a variety of Dutyholder and installation type, such as a large scale Operator plus a standalone Operator of an FPSO and a couple of mobile installations.[39] The inspection and enforcement regime is broadly similar to that of ONR.

131. In addition to offshore inspections Inspectors also undertake regular onshore meetings and investigations. Inspectors are also involved in strategic interventions and industry groups and close liaison with other regulators to ensure sharing of learning and experiences.

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[38] The relevant regulations are SCR2015: The Offshore Installations (Offshore Safety Directive) (Safety Case etc) Regulations 2015.

[39] FPSO = Floating Production, Storage and Offloading facility.

132. However there is nothing closely analogous in offshore regulation to the 36 License Conditions which dominate the safety regulation of nuclear sites. Corresponding conditions are imposed but in more diverse ways.[40]

133. There is some difference between offshore and ONR interest in the comparison of costs and monetised benefits. The tendency in ONR is not to seek information about costs. This has also been rare in offshore regulation in recent years, but only because the focus has been on aligning UK practice with EU and other international standards. Offshore activities are however inherently more amenable to cost/benefit calculations.

134. A feature common to ONR and HSE offshore practice is a concern for high transparency, although pressure for transparency in the nuclear case, with its exceptional political sensitivities and it physical closeness to local communities, is perhaps greater.

135. Overall it appears that offshore and regulatory procedures are similar where this is appropriate, but that areas such as reactor safety, the technology, the hazards and the nature of potential failures the differences are so great that they seriously limit the extent to which one might learn from the other.

3.4. International comparisons

136. Appendix C describes, with references, how the principal indicator of economic impact – that is the comparison of regulatory costs and benefits – is handled on the United States Nuclear Regulatory Commission (NRC) and the Canadian Nuclear Safety Commission (CNSC), together with an overview of wider OECD guidance on the topic. This section summarises these descriptions and draws out comparisons with ONR practice.

3.4.1. The United States Nuclear Regulatory Commission

137. The NRC regime is prescriptive in the sense that, in principle, it defines the technical specifications required to meet the meet the regime's safety standards. Regulators in the USA are required by an Executive Order of 1961 to apply regulatory analysis in connection with any "significant regulatory actions". The NRC has therefore produced substantial guidance on what analysis the NRC should undertake for changes in its regulations, and how this analysis should be done. The NRC's "Regulatory Analysis Guidelines" provide guidance on whether a proposed regulatory change should be subject to NRC analysis and what such analysis should cover. Its "Regulatory Analysis Technical Evaluation Handbook" provides more methodological detail.

138. These and other documents recognise the wide range of issues that usually need to be considered, not all of which can be monetised or even normally quantified. However the basic methodology is framed in terms of benefit-cost analysis.[41] The Guidelines and

[40] SCR2915 includes 41 Regulations (and 14 Schedules), but these are different in character from nuclear site licence conditions.

[41] 'Benefit-cost analysis' and 'cost benefit analysis' as used here are US and UK usages for the same concept.

Handbook are expected to be revised, but benefit-cost evaluation is likely to remain prominent in the regulatory analysis process.

139. The Guidelines (with more detail in the Handbook) identify the topics to be considered in the benefit-cost analysis. These include effects on the following.

- public and occupational radiation exposure
- costs to licensees
- costs to the NRC
- costs to State, local, or tribal governments
- health, safety, or the natural environment
- regulatory efficiency or scientific knowledge needed for regulatory purposes
- the efficient functioning of the economy and private markets
- safeguards risks

140. Adverse effects, such as increase in NRC costs or loss of environmental quality are described as "impacts". Beneficial effects, such as a reduction in NRC costs or improvement in environmental quality are described as "values". In the context of this current study it is noteworthy that "the efficient functioning of the economy and private markets" is included in the list.

141. The Guidelines cover the conventional basic issues in benefit-cost analysis, such as "[v]alue and impact estimates are to be incremental best estimates relative to the baseline case, which is normally the no action alternative." The "no action" alternative is not necessarily the same as the status quo. With uncertainty about the future in the absence of the proposed action, consideration of costs and benefits relative to multiple baseline cases may be appropriate. They further specify that the analysis should ideally identify and value costs and benefits by stakeholder category; impacts should be calculated by year; where possible performed in monetary terms, in constant dollars and discounted to present value. The Guidelines and Handbook provide a specific, recommended value (in dollars per person-rem) for exposure to radiation to be used in the calculations.[42]

142. The Handbook's discussion of what it describes as Value-Impact Analysis includes discussion of types of uncertainty and the techniques for addressing them, including Probabilistic Risk Assessment (PRA). The Guidebook and Handbook recommend that PRA techniques be used where feasible in arriving at "best estimates" of values and impacts. Certain attributes (public health, occupational health, offsite property and onsite property) should normally be calculated by using PRAs to estimate their expected values.

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[42] The NRC published in August 2015 a Draft Report for Comment on "Reassessment of NRC's Dollar Per Person-Rem Conversion Factor Policy". This is summarised at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1530/r1/ including a link to the full document. The Report proposed an increase in the value per person-rem from $2,000, set in 2004, to $5,100. This included several adjustments, the largest of which was the increase over that period in the standard US value for a statistical life. The period for commenting on the Draft Report has now closed, but to date no further action on this issue appears to have taken place. The values are based on a 'linear no threshold' extrapolation to zero from data on human health impacts of high radiation doses.

143. A distinction is drawn between new plant and "backfitting", in that the NRC can require backfitting of a facility "only when it determines…that there is a *substantial increase* in the overall protection of the public health and safety or the common defense and security to be derived from the backfit". No formal analysis is needed for a backfit requirement where regulatory action is necessary to ensure "adequate protection", defined as "that level which must be assured without regard to cost". This "Adequate protection" level is not formally defined.

144. Post Fukushima a re-evaluation by NRC staff concluded that the existing framework (including the Guidelines and Handbook) was sound and sufficiently flexible to address the issues raised. However the Executive Director for Operations subsequently proposed a number of ways in which the existing regime might be improved. A timetable for an 'Option 2' (now referred to as a "Regulatory Gap Analysis") was published in 2014. The second phase of the proposed work in revisions to cost-benefit guidance is still in progress, but is not expected to reduce the standing of such analysis.

145. The NRC regime shows similarities to and, more conspicuously, differences between US and UK conventions. The requirement for regulatory analysis is superficially similar to the UK requirements for regulatory Impact Assessments, but within a very different, NRC-specific context. The NRC concept of 'adequate protection' that must be assured without regard to cost is analogous in principle to the TOR/R2P2 'upper tolerability limit', but it is not formally defined. Post Fukushima the NRC developed its guidance for estimating offsite economic consequences, with more current data, and more advanced modelling. There does not however appear to be any work analogous to the COCO studies commissioned by the ONR. The NRC's requirement to undertake CBA, and its monetisation of personal radiation exposure is not mirrored in the ONR. On the other hand the ONR does use the same 'linear no threshold' assumption for health impacts in its formal justification of the Basic Safety Limit of 20 mSv per year for employees working with ionising radiation.

3.4.2. Canadian Nuclear Safety Commission

146. The role of cost-benefit information in the CNSC regulatory regime is very different from that in the US NRC regime. The CNSC does issue some guidance on the use of cost-benefit information, but this is much less specific than even the US NRC Guidance document. More substantially it is issued as guidance to regulated bodies that wish to use such analysis when submitting evidence to the CNSC in support of the body's proposed action. It is not intended to guide analysis undertaken by the CNSC itself.

147. The most recent development is the issue, in February 2016, of a Discussion Paper on "How the CNSC Considers Information on Costs and Benefits: Opportunities to Improve Guidance and Clarity". We provide here a very brief overview of the Discussion Paper and the comments from the industry made before the deadline of August 2016. (A CNSC response is expected soon.)

148. The CNSC perception of its own obligations to perform or require a cost-benefit evaluation is not clear. [43] It does however appear to recognize some obligation to analyse costs and impacts of its own new or amended regulations, and to present its results in a Regulatory Impact Analysis Statement (RIAS). It notes that in July 2015 it "began including impact statements along with draft regulatory [guidance] documents being issued for consultation". However, some industry comments noted that the CNSC does not say *how* it will perform its RIASs and called for the agency to spell out its own obligations more explicitly. They suggested that the CNSC should act more consistently with other government policies and guidelines such as The Canadian Cost-Benefit Analysis Guide.

149. The Discussion Paper and previous CNSC documents in this field include very basic principles, such as the need to state the rationale for the project; identify alternatives; forecast impacts; analyse uncertainties and use sensitivity analysis; and use an appropriate discount rate. But beyond this the emphasis is largely on the limitations of such analysis and the fact that "costs and benefits are only one consideration that the CNSC may take into account when making a decision, and this is always done in a manner that puts safety first". [44]

150. The CNSC uses the term 'as low as reasonably achievable' (ALARA) and says that "In implementing the ALARA principle, it must be determined whether the efforts to reduce doses are worthwhile." It adds that "understanding, good practice and feasibility" can help judge reasonableness, with the weighing of costs against benefits identified as a possible component of "feasibility".

151. The CNSC "does not recommend specific dollar values for a unit of collective dose saved, it is left to the licensee's discretion to set this value" (CNSC, 2008, p46). The regulatory dose limits to workers are the ICRP figures of 50 mSv in a year and 100 mSv over five years (CNSC, 2015). It explains that Canadian regulations also use many of the standards and guides of the IAEA.

152. (The CNSC also produces impressively clear and constructive publications for a general audience, such as CNSC (2013) and CNSC (2015) on radiation doses. Its formal responses (CNSC, 2008) to questions on the Peer Review of a Report for the Convention on Nuclear Safety are similarly clear and informative.)

153. The CNSC approach to analytical comparisons of costs and benefits has features in common with that of ONR. It looks entirely to regulated bodies for any such analysis in specific applications. It emphasises the limitations of formal quantification. It puts at

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[43] The 2000 publication on 'Considering cost-benefit information' (the first CNSC reference in Appendix C~~D~~) records rather blandly that "The Government of Canada requires federal regulation-making authorities to adhere to its related policies and processes in serving the public interest. This includes weighing the benefits and costs of proposed regulations, and applying government resources where they can do the most good. The CNSC follows federal policies and processes when it develops regulations."

[44] The limitations of formal analysis in public policy are indeed severe. But to say that "costs and benefits are only one consideration" makes sense only with restrictive definitions of these words – it may be that CNSC uses them here to describe only *monetised* costs and benefits.

least some significant emphasis on good practice. It is responding now more strongly to a regime for regulatory Impact Assessments for its own new regulations which has features in common with the UK IA regime. And the statement in the CNSC Discussion Paper that "costs and benefits are only one consideration that the CNSC may take into account when making a decision, *and this is always done in a manner that puts safety first*" (emphasis added) has shades of ONR philosophy. However its documentation is much more positive towards formal analytical approaches to comparing costs and benefits than is ONR. It also, in contrast to ONR, justifies its (virtually identical, ICRP based) radiation dose limits by reference to international standards rather than estimated fatalities.

3.4.3. The OECD and the OECD Nuclear Energy Agency

154. The OECD is a major proponent of Regulatory Impact Analysis (RIA) and has described cost-benefit analysis as "the core method of RIA." But the OECD Nuclear Energy Agency (NEA) does not recommend any specific method in the context of nuclear regulation.

155. It has been explained to us by ONR that the NEA at one time aspired to developing a standard approach to nuclear safety regulation, but the legal and probably cultural differences were too severe to make progress. However its Multinational Design Evaluation Programme is an important channel of communication between nuclear safety regulators, especially in relation to new nuclear reactor designs. It describes its two main lines of activity as:

- exploration of opportunities for harmonisation of regulatory practices;
- cooperation on the safety reviews of specific reactor designs.

156. However on regulatory approaches and on methods of comparing costs and benefits the NEA explicitly recognises the wide current diversity and does not pass judgment

4. Review of ONR incentives and principles

157. This chapter opens, in section 4.1, with an examination of the incentives facing ONR as an institution and facing ONR inspectors. Section 4.2 discusses the comparison of costs and benefits within ONR's philosophy and methodology. Section 4.3 comments on enabling regulation.

4.1. Institutional and personal incentives

158. The incentive structure facing ONR as an institution and ONR inspectors is complex. Some of these incentives (which can apply differently to different ONR programmes) are recorded below as factual context for the rest of this chapter.

i. **Weak financial incentives**: The principle of charging bodies for regulation of their external impacts promotes economic efficiency, insofar as the fee charged to the regulated body covers at least part of the cost of the externality that the body imposes on others. But it produces less helpful incentives for the regulator.[45] As a self-financed body the regulator is largely released from the disciplines of annual budget negotiation with a government funder. And once staff have been allocated to tasks, to which all of that allocated working time has to be booked, there is no conventional market incentive for the evolution of more cost effective methods.

ii. **Strong professional and reputational incentives**: Safety regulators – both individuals and institutions – are tasked with ensuring low safety risks. This is their professional expertise, on which like all professionals they mostly focus. As individuals they are incentivised to demonstrate more rather than less activity to this end. The measure of success, especially at the institutional level, is the absence of accidents and a low level of reportable incidents.[46] In responding to these incentives regulators may face little counterbalancing incentive, beyond the limited constraint that ALARP imposes on costs, and guidance on the overriding importance of compliance with the law (e.g. ONR (2016a), para 5.20), to take into account the costs imposed by their decisions.

iii. **Statute law and natural monopoly**: UK Statute law, as generally in advanced economies, gives powerful authority to safety regulators. This reinforces the natural monopoly that the regulator typically holds: in practice it is generally the regulator who has the final say on whether the regulated body can or cannot continue its business (although of course, ultimately this can be appealed to a court). This might be described as a contextual factor rather than an incentive, but

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[45] A minor qualification, suggested by one transport applicant, is that charging may embolden a regulated body to give stronger feedback to ONR if it feels it is receiving 'poor service'. But our discussions suggest that this is not a material issue. Perhaps more important may be the effect of self-financing on ONR's ability to fund the staff needed to provide the quality of service that it seeks. But it is beyond our scope to examine this.

[46] In HSE/ONR terminology an accident results in injury or ill health and an incident is either a near miss or a set of conditions or circumstances that have the potential to cause injury or ill health, such as the leak of a dangerous material into a cell designed to contain such a leak. ONR publishes quarterly reports of any incidents that meet 'ministerial reporting criteria'(ONR, 2016b).

it will affect attitudes and behaviour of inspectors and those whom they regulate.[47] It strongly suppresses challenges by regulated bodies in other than very extreme circumstances, or when challenge is explicitly encouraged by the regulator.

iv. **Case law**: The language of "gross disproportion" (between costs and safety benefits) is deeply embedded in current ONR guidance, reflecting the wider application of the term in health and safety regulation. [48] The relevant TAG, for example, explains that: *"the onus is on the licensee to implement measures to the point where the costs of any additional measures (in terms of money, time or trouble – the sacrifice) would be grossly disproportionate to the further risk reduction that would be achieved (the safety benefit).*" It adds that *"Advice from HSE lawyers is that, provided the risk is more than fanciful, the courts would still seek 'gross disproportion'... even at the* [very low] *TOR Broadly Acceptable level."* (ONR, 2017, paragraphs 1.3 and 5.4(8)) (Emphasis as in the original). But there is no acknowledgment that the judgment from which the "gross disproportion" language is drawn is one precedent, among others, for defining the statutory criterion of "reasonable practicability". We discuss this in section 4.2.2.1 below.

v. **High vulnerability to political, media and NGO pressures**: Nuclear industry risks, to a perhaps unique extent, tick nearly all of the "fright" boxes in public perception. To most of the public the risks are involuntary, inescapable, arise from an unfamiliar source, are man-made rather than natural, are seen as having hidden and irreversible health impacts, and threaten future generations. Many people also associate the nuclear industry with nuclear weapons, and the industry is an example of large-scale, advanced technology controlled by major companies, of which many are suspicious. This creates two challenges.

   a. One, widely recognised, is that any serious nuclear accident or incident is likely to create major political and media storms, with serious risk of lasting damage to political and regulatory reputations.

   b. The other is pressure on the safety regulator to avoid anything that might be taken to imply even a hint of regulatory capture by the industry.

vi. **Regulatory culture**: Whatever the formal guidance faced by the individual inspector, the ways in which this is implemented is likely to depend heavily on the culture promoted and sustained by the regulator's top management. This is recognised in ONR's Regulatory Assurance procedures and the Enabling Regulation initiative. But cultural change takes time to diffuse, and maintenance of a positive culture needs constant monitoring and reinforcement.

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[47] It is recognised in the ONR Regulatory Assurance role, and central to the principles of Enabling Regulation, that in the "repeated game" that is the regulatory relationship, *trust* is or should be fundamental. But the enforcement powers of ONR have a big effect on some inspectors and always affect the regulated party.

[48] The Court of Appeal comment on gross disproportionality by Asquith LJ (in the civil law case of Edwards v. National Coal Board, [1949] 1 All ER 743) is set out in Appendix A, section A.3.2.

4.2. Comparing costs and benefits: ALARP and gross disproportionality (GD)

159. Economic impact is about social costs and benefits. If resources are used to produce more benefit than they would in any realistic alternative use, this optimises their economic impact.

160. It would be convenient for policy-makers, and for the economists who advise them, if costs and benefits could all be expressed accurately and in the same units. Unfortunately, in many areas of public policy – including safety regulation – there will usually be significant uncertainties and important factors that cannot sensibly be monetised. Some factors may even be difficult to *quantify*. Informed judgment is therefore required.

161. The legal criterion for such judgments is enshrined in law as SFAIRP, described in practical application as ALARP. At the time of the HSW etc. Act, 1974 the expression "reasonably practicable" was interpreted by HSE in terms of the "grossly disproportionate" criterion noted in section 4.1.

4.2.1. Current practice

162. It is notable, though understandable, that the principles of enabling regulation (set out in Appendix A and discussed in section 4.3 below) do not explicitly address the issue of cost/risk trade-offs, or "cost effectiveness", which is fundamental to ONR's economic impact. ONR's published mission *does* refer to efficiency: "To provide efficient and effective regulation of the nuclear industry, holding it to account on behalf of the public" (ONR, 2016d), where this is expanded by a list of "key outcomes" that do not necessarily target *economic* efficiency:

    - A nuclear industry that has a culture of continuous improvement and sustained excellence in operations.
    - All of our stakeholders value our work.
    - A nuclear industry that controls its hazards effectively.

    These targeted outcomes are excellent but, again understandably, they do not clearly include the concept of possible trade-offs at the margin between risk and cost.

163. ONR practice typically does not involve explicit cost-benefit comparisons. This is because most interactions are to establish compliance with codes and standards, and in practice "relevant good practice" very often provides a sufficient benchmark for ensuring that costs are not disproportionate. The norm here is that the safety regulator should not need to know of costs. Costs are seen as an issue for the regulated body to raise, if it feels that the ONR requirement is so disproportionate that it can be shown to go beyond ALARP.[49] We do not question this general approach. However a deliberate lack of concern with costs, which was communicated to us in our conversations with ONR staff, makes it less likely that decisions will always be economically efficient. And

[49] Signalling to dutyholders that costs will be considered only if they are grossly disproportionate (which is a difficult thing to show) means dutyholders must feel very strongly even to broach the topic

from time to time, as ONR acknowledge, cost-benefit trade-offs really do need to be addressed explicitly.

164. The concept of ALARP is long established and, as noted earlier, is still tied in ONR and HSE guidance to the Asquith LJ 1949 comment that costs need to be incurred to reduce risks "to the point where the cost of any additional measure would be grossly disproportionate". In other words expenditure on risk reduction should be disproportionate. Taken literally, as in current guidance and sometimes in current practice, this is not consistent with optimising economic impact, which would require that the marginal costs are proportionate to the associated (broadly defined) benefits.

165. HSE developed in the Tolerability of Risk (ToR) framework for nuclear plants in 1988, which was widened to all HSE regulation (applying to other industrial sites) in R2P2 in 1999, a quantitative "modern interpretation" of the Asquith LJ 1949 case law. This is explained in paragraph 5.4(8) of the ONR TAG on the demonstration of ALARP (ONR, 2017). It establishes 'gross disproportion factors' of 2 to 10, against a baseline of the monetised costs and benefits in a conventional cost benefit analysis. These factors may reflect impacts that the monetised analysis omits (such as the effects of a major accident on the nuclear industry and future energy policy, which were beyond the scope of COCO-2). Or high factors may apply to activities close to the ToR upper tolerability limit, such as a BSL.

166. It is certainly good practice to recognise that monetised analysis often omits significant impacts that cannot sensibly be valued explicitly in monetary terms, and to allow for this. And it is reasonable to have some extra weighting against activities that are close to an absolute limit where the risks are judged to be intolerable (even though these limits may have substantial conservatism already built in). In other public services such adjustments would be seen in terms of achieving *proportionality* between costs and benefits, rather than disproportionality, however. Handling such adjustments by applying a multiplier to the monetised costs risks appearing arbitrary. And applying a factor of 2, even if risks are well known and extremely low, would not be seen as good practice in other public services, especially, though not only, if public funds were being spent that might otherwise be spent saving lives elsewhere. HSE deserves much credit for rationalising the Asquith LJ words in this way in 1988. But today, the natural concern to "err on the side of safety" would typically be met by conservative standards (as now) combined with case by case, transparent professional judgment as to when these standards should tightened.

167. We have no further comment on the above quantitative interpretation of gross disproportion, which ONR has provided to us. However we did not find widespread understanding of this interpretation in the field, perhaps because the monetisation of costs and benefits is, for good reason, very rare in ONR. Even so, the impact of the guidance on disproportionality goes far beyond its potential (limited) use for monetization. Embedded more strongly in the culture of those ONR officials to whom we spoke are more general, absolute statements in the TAG on ALARP, such as:

    - Para 1.3: *"... the onus is on the licensee to implement measures to the point where the costs of any additional measures (in terms of money, time or trouble – the sacrifice) would be grossly disproportionate to the further risk reduction that would be achieved"* (emphasis as in the original).

- Para 5.2: *"The essence of a demonstration that risks have been reduced ALARP is to show that the "costs" (sacrifice) of improving safety any further would be grossly disproportionate to the safety benefits that would accrue …"*

- Para 6.2: *"Unless the sacrifice entailed in moving towards the ['new design'] benchmark is grossly disproportionate to the safety benefit, the licensee should make that move."*

- Annex 1: ALARP Checklist: *"For measures deemed not reasonably practicable, has the licensee demonstrated gross disproportion?"*

168. We are told that HSE solicitors and counsel advise that the Asquith LJ wording is the "key precedent" for interpreting the term "reasonably practicable". This is clearly true in the context of HSE/ONR guidance, where it has ruled for decades. However within the courts judicial opinions on its status differ. In our wide review of ONR guidance we have seen only one, low-key, acknowledgment of this.[50] External suggestions that HSE should re-examine how the 1949 case law on SFAIRP is interpreted have been routinely rejected as ill-informed. We summarise, in Appendix A, (Section A.3.1) some of the points typically made by HSE and others in rejecting such suggestions, drawing on the HSE response to a House of Lords Report in 2006. We accept that many of these points are good ones, and bear them in mind, along with advice from ONR, in the following reflections.

4.2.2. Reflecting on gross disproportion

169. HSE's and ONR's role is to enforce the law. Our own expertise is not in the law, and we do not seek to opine on it. We can however note what is said by lawyers, including senior judges, HSE's legal advisers, and legal commentators. Our impression is that the law and legal arguments embrace a sophisticated interpretation of reasonable practicability, and this is relevant to our economic perspective on safety regulation. We address the issues here in three dimensions: the legal history of reasonably practicable; logic, politics and institutional reality; and implications for ONR.

4.2.2.1. Legal history of reasonably practicable

170. We appreciate that, although the term reasonably practicable is central to HSWA 1974 and so defines current statute law, it had already been applied in health and safety law for many decades.

171. Interpretation of the term is not further developed in the HSWA and it appears to be accepted in the courts that there is no unambiguous case law to clarify it. (We consider in the next section whether or not further clarification might be in the public interest.) Historically HSE/ONR has maintained that a safety measure should be implemented unless its cost is grossly disproportionate to the benefit. However we note that, in recent

[50] "Ultimately, the courts determine what is reasonably practicable in particular cases." (ONR, 2014, paragraph 17).

years especially, concerns have been raised about the concept's definition and application.

172. In 2006 the House of Lords Select Committee on Economic Affairs (House of Lords, 2006b) said: *"We are concerned that regulatory requirements concerning risk appear to rely heavily on a range of concepts which may not be sufficiently well-defined to enable the framing of useful operational guidelines. The danger inherent in the use of such ambiguous concepts is that they may encourage excessively risk-averse responses from policy-makers."* Their Report presented the House of Lords case of Marshall v Gotham Co Ltd ([1954] AC 300, HL) as follows.

> *"In addition [to Edwards v NCB 1949, in the Court of Appeal], the issue of reasonable practicability was considered by the House of Lords in a 1954 case, the head-note of which states:*
>
> > *'The test of what is (reasonably practicable) is not simply what is practicable as a matter of engineering, but depends on the consideration, in the light of the whole circumstances at the time of the accident, whether the time, trouble and expense of the precautions suggested are or are not disproportionate to the risk involved, and also an assessment of the degree of security which the measures may be expected to afford'.*
>
> *"We should note that while the first of these legal judgments refers to 'gross disproportion' the second requires only that costs should not be 'disproportionate' to the risk reduction concerned. Nonetheless, the HSE has continued to refer to gross disproportion [which] has led to considerable confusion[…]."*

173. Elliott and Appleby (2011) provide further comment on the precedent and provenance of the language used by the judges in the Marshal v Gotham case on the meaning of 'reasonably practicable': *" None of the judges used the term 'gross disproportion', although two referred to Asquith LJ's judgement. Three of the judges preferred Coltness Iron Co v Sharp [1938] AC90, in which Lord Oaksey said: "[W]hat is 'reasonably practicable' depends upon a consideration whether the time, trouble and expense of the precautions suggested are disproportionate to the risk involved." For Lord Oaksey, the test was whether the burden is 'disproportionate', not 'grossly disproportionate'."*

174. In 2008 the House of Commons Work and Pensions Committee said: *"We are concerned that the test of 'reasonable practicability' introduces a lack of clarity that can increase the burden on employers in meeting their health and safety obligations."* The Committee recommended (to no effect) that the Law Commission review the term.[51]

175. In the recent joined appeals against convictions under the HSWA of R v Tangerine Confectionery and Veolia [2011] EWCA Crim 2015, the Court of Appeal said only that reasonably practicable depends on all the circumstances of the case, "*…including,*

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[51] Later in 2008, in the House of Lords case of R v Chargot (HoL, 2008), Lord Hope set out the aims of the HSWA, saying that "*It is not its purpose to impose burdens on employers that are wholly unreasonable. Its aim is to spell out the basic duty of the employer to create a safe working environment.[…] It is directed at situations where there is a material risk to health and safety, which any reasonable person would appreciate and take steps to guard against.*"

principally, the degree of foreseeable risk or injury, the gravity of injury if it occurs, and the implications of suggested methods of avoiding it".

176. That Court's judgement referred in this context to Baker v Quantum Clothing (Supreme Court, 2011). This was a civil case relating to an employee's hearing loss, arising from sound levels that met those of the then-prevailing British Standard, but, from data in a draft EC Directive, could have been seen to be harmful to some people. The Court, by three to two, supported the employers. Two of the five Judges expressed no view on gross disproportion, which was not a significant issue in that case, but the others did express views, two of them explicitly. One of the dissenters, Lord Kerr, said (paragraph 184) that he agreed with the Court of Appeal Judge that, referring to Asquith LJ, "for the defence to succeed, the employer must establish a gross disproportion between the risk and the measures necessary to eliminate it." Lord Mance however, in delivering the Court's judgment, and following discussion of 'reasonably practicable' (his paragraphs 81 to 83) said in paragraph 84 that:

> "*A further aspect of para 84 in Smith LJ's [Court of Appeal] judgment is the suggestion that 'there must be at least a substantial disproportion' before the desirability of taking precautions can be outweighed by other considerations. This theme was developed in paras 82 to 84 of her judgment, on the basis of dicta in two cases prior to Marshall v Gotham. But it represents, in my view, an unjustified gloss on statutory wording which requires the employer simply to show that he did all that was reasonably practicable.*"[52]

Lord Dyson, in discussing "reasonably practicable", conspicuously ignores the words of Asquith LJ. Lord Dyson said that *"the classic exposition of reasonable practicability is to be found in* Edwards v National Coal Board *[1949] 1 KB 704. Tucker LJ said at p 710: 'in every case it is the risk that has to be weighed against the measures necessary to eliminate the risk. The greater the risk, no doubt, the less will be the weight to be given to the factor of cost.'"*

177. Lord Mance's comment has unsurprisingly been widely discussed by legal commentators. Elliott and Appleby conclude, from this and other considerations, that "*There is no basis – in law or logic – to set the bar at 'grossly disproportionate' to determine whether a safety measure is reasonably practicable.*"

4.2.2.2. Logic, politics and institutional reality

178. Literal application today of "gross disproportion" (GD) poses analytical questions.

179. One is the question "proportional to what?" In paragraph 5.4(8) of the relevant TAG, as noted above, this question is answered for the rare cases where many of the costs and benefits are monetised. It is explained a gross disproportion factor applied to include the analysis for impacts that are not monetised, including some appropriate "margin for safety", as most people would recognise in, for example, the design of a bridge. However the general concept of ONR demanding 'disproportionate' expenditure extends more widely, to situations with benefits that are not explicitly valued.

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[52] Lord Mance has since been appointed to Deputy President of the Supreme Court.

180. So far as we know there is no information on what cost baseline Asquith LJ had consciously in mind, if any, but his speaking of 'disproportionality' of costs makes no sense without some sense of the value of the safety foregone if the cost is not incurred. In 1949 there were no formal valuations of fatality or injury risk, but whatever figures were consciously or subconsciously in his mind will almost certainly have been much lower than those recognised today.[53] Asquith LJ's "gross disproportionality", with its 1949 baseline, would be amply achieved by "proportionality" relative to today's baseline, following massive real increases in the perceived social costs of health and safety risks (mostly since HSWA 1974).

181. Another question is that of the effect of GD on how safety expenditure is justified. As we note in sections 2.3 and 4.2.2.3, there are legitimate reasons for requiring safety standards that cost more than the *direct, monetised* benefits of the risks (and expected levels of harm) that they mitigate. This is closely related to the generally accepted concern to "err on the side of safety". But the relevance of several such factors to GD is not clear (Bearfield, 2006). These might include, for example, variations in societal values associated with certain types of risk and/or uncertainty in the quantification of risk; and sometimes national political and wider industrial impacts might need to be considered, whether or not all such considerations fall formally with the ambit of SFAIRP. A reluctance to consider in formal terms what underpins 'gross disproportion' precludes constructive development of such questions. Such development might lead to deeper understanding of and better guidance on the levels of special concern that are appropriate for different types of hazard or levels of risk (beyond that already provided by TOR).

182. A thoughtful exploration of this situation, published by Burges Salmon LLP (Jackson, 2014), describes the gross disproportion test as "the Elephant in the room", and notes that "any attempted debate on it is avoided or swiftly shut down." It records accurately that "All current messaging in Health and Safety reform emphasises proportionality,"[54] but that this contrasts with the commitment to disproportion. One consideration raised is the infraction case brought against the HSE by the European Commission in 2007, summarised in Appendix A (section A.1). There appears to be some legitimate concern not to undermine that European Court ruling, which relied upon gross disproportion.

4.2.2.3. Implications for ONR

183. It does appear that HSE/ONR are justified in opposing calls by Select Committees and others to define reasonably practicable more precisely. Real world circumstances are

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[53] As discussed in Appendix A (section A.3.2), the implicit valuation of fatality risk recognised by a court at that time will have been lower – by a huge factor – than the values now used. Evans (2013, p 141) notes that "the 2009 British official Value of a Prevented Fatality, based on willingness-to-pay (WTP), was £1.59 million, or about 60 times greater **(**in real terms**)** than the 1949 compensation" paid to the widow in the Edwards v National Coal Board case.

[54] As a modest example, we note that HSE stresses the need for local authority decisions to be "proportionate". See for example, the short guide to "Striking the balance …in the Fire and Rescue Service" (HSE, 2010). This is aimed largely at *risk assessment*, to discourage local officials from overestimating risks and perhaps banning activities inappropriately – and not more broadly at implementing safety measures. But the general message of the guidance is to *avoid* imposing disproportionate restrictions or other costs on dutyholders or the general public. (Of course, HSE is not here expressing any legal opinion.)

probably too diverse and unpredictable to do better than to clarify the law by the slow accumulation of precedents. And in any case, constructive open debate on a clearer definition might be politically impossible.

184. The one situation for which it is defined, as outlined in section 4.2.1 above, is as "disproportionality factors" applied to monetised estimates of costs or benefits. But such cases are in practice very rare.[55] Perhaps for this reason it is not conspicuous in ONR guidance and does not appear to be widely understood. However this specific application of the gross disproportion criterion might in principle be close to the views of many critics. A factor of 2 would be excessive in most public appraisal contexts, but some "erring on the side of safety" is reasonable, and given the degree of uncertainty about the types of hazard and risks being quantified, a factor of 2 may be appropriate. In any event, a factor of 2 is unlikely ever to be considered "grossly" disproportionate. And as risk increases towards an intolerability limit, it is not unreasonable to require a raising of the bar as that limit is approached, rather than applying a cliff edge cut off at some specific level of risk. However, as things stand, there appears to be widely *in practice* a literal requirement of 'disproportionate' safety expenditure by licensees. This is not consistent with optimising ONR's economic impact as a regulator – nor of course with Treasury guidance. ONR's task is of course to enforce the law, and the fact that some judges interpret reasonably practical in terms of the Asquith LJ precedent is very material. But opinion within the judiciary, up to the highest level, does not appear to be united on this point.

185. Meanwhile institutional structures in the nuclear industry are changing as the industry itself changes. Existing UK nuclear sites are increasingly decommissioning sites, fully funded from the NDA budget. The NDA and BEIS explicitly look for spending that is at the margin *proportionate*, not disproportionate, to the social benefit that it brings.[56]

186. We therefore question whether the terminology of requiring "disproportionate" safety expenditure is sustainable into the long term. Looking instead for "proportionate" expenditure – taking into account all relevant societal benefits – would have no effect on the application of relevant good practice, and in other cases would normally lead to outcomes very similar to those under the current regime. But it could improve the

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[55] The only case where we met such a factor in our interviews was the application of a factor of 10, which appeared to have been set at that level because of the large hazard.

[56] At the international (European) level we note that the draft WENRA Report for public consultation (WENRA 2017) prepared by an Ad-Hoc Group, led by the UK ONR, developing a common approach to Article 8a of the EU Nuclear Safety Directive.56 This explains how an initial proposal to include the UK terminology of "grossly disproportionate" was amended as it was unclear how it might "be readily adopted or interpreted in some national legal frameworks".

The current wording therefore interprets "reasonably practicable" in terms of "relevant good practice "and regulations commensurate with the magnitude of the radiation risks and their amenability to control" and the application of safety measures "Unless the sacrifice entailed in moving towards the benchmark is clearly demonstrated to be disproportionate to the safety benefit."

This international development of course has no direct implications for the interpretation of English law. But it is interesting to see a group of international nuclear regulators (in sharp contest to the EC officials of a decade ago) proposing and approving the terms "commensurate" and advising *against* requirements that would be "disproportionate" to the safety benefit. This language is materially different from a standard that would only reject measures whose costs are "*grossly* disproportionate", while endorsing those that are disproportionate.

quality of regulation, by obliging more careful thought about exactly what determines proportionate expenditure and how this can be delivered – perhaps with more nuanced assessment of non-monetised impacts than the current 'disproportion factors'.

187. A ripe time for such radical change may be some way away. But in the shorter term there is a case for aligning some guidance and training more closely with the law as it stands. It is not accurate for example to refer to "the legal test of gross disproportion" (SAPs, paragraph 698), since the legal test is "reasonable practicability", which is to be interpreted by the courts. Nor is it quite right to advise inspectors that "provided the risk is more than fanciful, the courts would still seek 'gross disproportion'" (TAG on Demonstration of ALARP, paragraph 5.4(8), since a court may or may not take that view. Nor does it appear correct to say (as it currently does in the same TAG) that "no subsequent legal proceedings […] have countered these views", when there are examples of legal opinions at the highest level that appear to differ.

188. Moving away from the language of (gross) disproportion would also be more consistent with other areas of public policy outside safety regulation. When government bodies decide how to spend scarce public funds – for example, in deciding what levels of funding to commit to reducing or remove radiation risks from NDA sites – this is necessarily balanced against alternative uses of such monies, such as funding to maintain or improve the health impacts of the NHS.

4.3. Enabling regulation

189. We found within ONR a range of perceptions of Enabling Regulation (ER). Some staff appeared to feel that it did not apply to their particular role. Several took on the message of "be cooperative" but little more. One felt that the article in the December 2015 issue of Regulation Matters, with its statement that "This is not new" suggested that it was no more than conventional senior management exhortation.

190. There is a range of perception also among licensees and others. It has been put to us by licensees that ER says nothing about the balancing of costs and benefits and currently this is true. But regard for costs does appear to be an area in which ONR's economic impact (and associated contribution to national welfare) could be improved and this would be consistent with the principles behind ER.

191. The initiative appears to be focused heavily on Sellafield and this impression seems to be shared across the industry. Another phrase in the December 2015 article is "This is a modern regulatory approach", which meshes with the comment by an experienced industry interviewee, reasonably well disposed to ONR, that ONR regulation in his experience had previously been "rather old fashioned". Sellafield is certainly seen by participants and many observers as "a modern approach". It was not clear that elsewhere in ONR enabling regulation is seen in this way.

192. Behavioural principles are challenging to transmit throughout a large institution with staff members who face a range of widely differing circumstances. Detailed documentation may well be inappropriate for such an initiative. It might even set it back. But there may be scope for a structuring that reveals more clearly the depth of the initiative. We understand that some guidance is being prepared.

193. A concern expressed by Sellafield Ltd and also more widely across the industry was the sustainability of an initiative of this kind.

194. We note that in the Enabling Regulation principles (reproduced in Appendix A), the principle headed "Risk appetite" focuses on the risk to ONR of appearing to submit to regulatory capture. It states that "It is important that ONR senior management/board accepts any risks being taken [by adopting a cooperative approach to regulation] and is prepared to fully support those undertaking the work if the risk should materialise". It has been put to us that the potential for failure of such support, should such a case materialise, illustrates one way in which the initiative is vulnerable.

195. Enabling regulation is obviously far from a default mode to which regulation will gravitate. It would die in the absence of lasting top level monitoring, commitment and encouragement. To some extent benefits can be "wired in" by formal mechanisms and processes (such as the monthly Regulatory Interface Meetings at Sellafield). But the fundamental behavioural issues need constant reinforcement, and an absence of contrary messages from senior management.

196. There is also the possibility that the drive for enabling regulation could be set back by some politically embarrassing accident or incident that led to a political demand for "stronger", more adversarial regulation. This suggests that there may be great benefit, as we expect is recognised within ONR, in publicising at a high level within government the success of enabling regulation and the great importance, for productivity, of its being maintained.

5. Conclusions

5.1. The economic impact of ONR

197. History demonstrates that, for high hazard industries, society needs a strong and independent regulator. The nuclear industry stands as a prime example. ONR's principal function is to ensure that the nuclear industry is held accountable for the hazards that it poses, and that the risk of a serious nuclear accident is kept at an extremely low level. The evidence suggests that ONR fully meets this responsibility for the nation. No one we have spoken to in this study has questioned this.

198. This achievement is of great value. It is not however feasible to derive for this a meaningful, explicit and comprehensive monetary valuation. There are several reasons for this. Factors such as public and political confidence defy monetisation and, as with many major regulatory regimes, there is no meaningful counterfactual against which to compare the current state of the world.

199. It is possible to review individual regulatory decisions and regulatory conventions and processes against the criterion of optimisation in the public interest. In the case of nuclear regulation, however, even this is especially difficult, as there is so little data on the costs of individual regulatory requirements, or their benefits. It is striking that there is no monitoring of the costs to regulated parties arising from ONR regulation and **this lack of cost data is a notable gap in the regulatory framework.** Nonetheless some meaningful judgments can be made.

200. The reformed regulatory structure and culture at Sellafield since April 2014 is widely recognised as a major contribution to productivity at that site, relative to the many previous years when the site was performing poorly, perhaps mainly because of over rigid safety regulation. **By focusing on the bigger picture, the new arrangements at Sellafield have made it possible to deliver far greater benefits from more cost-effective and rapid rehabilitation of the site.**

201. Nuclear transport regulation is now seen by Applicants as broadly satisfactory, having recovered from a period of decline to 2013, attributable to the extended transitional difficulties of its transfer from DfT to ONR. **This study found no evidence that ONR's nuclear transport functions, mainly of enforcing international standards, could now be carried out significantly more cost-effectively.**

202. In the safety regulation of operating reactors and other operating facilities, and of decommissioning and restoration sites other than Sellafield, ONR may sometimes apply more costly safety standards than in other countries – but the evidence for this was anecdotal. However across these programmes licensees appear to have good professional relationships with the senior inspectors with whom they are dealing. And, on the basis of relatively thin evidence, **it appears that the regulatory fees of ONR, for reactors and other operating facilities, are significantly less than those in the US, albeit at least in part because the UK's non-prescriptive regulation shifts the analytical burden more heavily onto regulated parties and away from the regulator.**

203. **There are two programmes in which, for different reasons, the economic impact seems to merit further consideration.** One is the GDA process, where inspectors face an incentive structure that is not helpful in this respect. The other is non-nuclear transport, where (at the time of our study) the feedback from regulated parties was that the general quality of front line inspection was disappointing. As a separate issue in non-nuclear transport, ONR fees for package design assessment appear to be too high for at least some SMEs to continue to undertake such work.

204. Among licensees there is low level dissatisfaction, or irritation, across several operational programmes, with the attitudes and actions of a minority of specialist inspectors, to whom the enabling regulation message of mutual respect and proportionality has not yet reached.

205. **NDA funding of a complete operation, as with Sellafield, Magnox, and part of nuclear transport, correlates closely with operator satisfaction with the safety regulatory regime, but this is not surprising.** ONR's fees are in these cases funded by the NDA. And it may be that ONR inspectors more easily see themselves sharing a common, public service cause (namely, ensuring the safety of nuclear sites) with the operator, as opposed to dealing with a private sector commercial enterprise. This arrangement appears also to promote cost-effective regulation. The success of these arrangements depends however on proactive monitoring and management by both ONR and NDA. The operator was far from satisfied with safety regulation in pre-2014 Sellafield.

206. NDA programmes do however face the "problem" of sites where levels of radiation are declining to very low levels, and therefore may no longer be suited to existing regulatory frameworks. **There is some feeling that there is scope for development in ONR's wider strategic approach to issues such as the final decommissioning of sites.**

207. The EPR containment vent issue appears eventually to have been resolved to a satisfactory conclusion, but **the costly process by which this was reached reveals the absence of satisfactory mechanisms for resolving such serious and persistent technical differences**.

208. **Promotion of the case law interpretations of "reasonably practicable" as requiring disproportionate safety expenditure is difficult to square with the Regulators' Code or the Growth Duty.** The ONR explanation that "inspectors employ proportionate approaches to cost when assessing dutyholders' compliance with the law" (ONR, 2015) does not address the issue of how the law is interpreted. Inspectors need to be aware that a court may adopt this interpretation, but that it is not the only interpretation recognised by the courts. They should also be more aware of the ONR's sliding scale of disproportion factors from 2 to 10 for defined low and high risks. A position that 'reasonable practicability' requires measures that are "proportionate" to the hazard and risk, albeit often including a substantial margin of safety where the direct benefits of mitigating risk are difficult to quantify and/or to make precise, might be developed as a sustainable and less controversial convention.

209. Examination of the US NRC and the Canadian NSC regimes reveals interesting differences and similarities between these two regimes and between each of them and

the ONR regime. For example the US NRC places much emphasis on its own benefit-cost analysis, reflecting its prescriptive regime, and explicitly monetises radiation doses.[57] The CNSC in contrast provides high level guidance for the preparation of cost-benefit analysis by the bodies that it regulates, and does not monetise radiation dose. However our review has not provided any basis for comparing the balances they strike at the margin of costs and benefits with the balance struck by ONR.

5.2. Potential for improving ONR's economic impact

210. In this final section we review potential steps to improve ONR's economic impact. Some may be culturally and/or politically challenging. We group them under the main headings of 'Improving Information', 'Developing and maintaining culture', and 'Developing analysis and strategic frameworks''.

5.2.1. Improving information

5.2.1.1. External comment and comparisons

211. ONR is a first class nuclear safety regulator and sees itself as such. This is good for morale and for motivation to maintain this standard. But well-justified pride may weaken incentives to seek out potentially critical external comment or comparisons. This is partly belied by the commissioning of this current study, which clearly fits this role. Even so, gaps remain.

212. One gap is feedback from regulated bodies. It is true that, in most programmes, ONR actively encourages challenge on specific regulatory decisions. However there has never been, to the best of our knowledge, any independent survey to record the opinions held of ONR by any set of regulated bodies. **Even in cases where ongoing relationships are good, with regular meetings, it is likely that occasional independent surveys would reveal substantive, constructive criticisms that would not otherwise be heard. In other cases such independent survey work would most likely reveal significant problems that would otherwise escape the attention of ONR management**. Our own interactions with regulated bodies and public sector stakeholders provided rich and detailed feedback that we would see benefit in repeating, at least periodically.

213. Our impression is that **ONR often may not recognise the effects of its significant power relative to bodies that it regulates**. It is very rare for a regulated body to challenge or openly criticise the ONR, except in situations which the regulator clearly sees as open to discussion. In our studies we found only one case (the EPR FCV) where the regulated body challenged the clear wishes of ONR inspectors. The costs of this process to the requesting party were significant – although ultimately, these costs were less than the potential costs that NNB avoided by not incorporating an FCV system.

[57] We understand that such valuation has in the past been considered in the UK, but rejected. This, together with the basis of the 20mSv BSL, is discussed briefly in Appendix A, section A.2. However, even if benefits are not monetised in this way, there may be a case for deriving the implicit cost per mSv of specific measures, in considering whether they might be strengthened or relaxed – or indeed, made more consistent across different contexts.

Inspectors should be advised that the absence of criticism, or spontaneous action by a responsible and competent regulated body to implement what they know the regulator would require, does not mean that the regulated body is necessarily content.

214. A second area is that of systematic, quantitative international comparisons of factors such as regulatory costs and standards as applied in practice. There are many difficulties in this field, because of differing legal and institutional structures and regulatory conventions. But at present the only information available on comparative costs, or views of regulated bodies, appears to be ad hoc and sketchy. **There could be a case for investigating what information could be collected, without disproportionate effort, to help indicate how ONR's economic impact in specific types of regulation compares with some other national regulators**.

215. A more occasional area of concern is that of technical judgments when unreconciled disagreements persist on major decisions between world class experts. As noted above, the FCV issue revealed efficiencies in the current process for resolving such issues.[58] Perhaps such a process would include the potential, in exceptional circumstances, to draw on external technical expertise.

5.2.1.2. Knowledge of costs

216. It is reasonable, particularly with non-prescriptive regulation, that ONR inspectors should focus on safety, while regulated parties focus directly on the balance of safety and cost. But this can be carried too far. As noted in Chapter 3, in the Sellafield and Magnox programmes, where expenditure is constrained by an annual public expenditure budget, decisions will by default lean towards cost-effectiveness, provided there is trust and respect between regulator and operator. And in transport the prescriptive regime limits the scope for assessing cost / benefit trade-offs.

217. However **there does appear to be a case, in some contexts, for introducing procedures that make inspectors more aware of both the resource costs and the technical implementation costs that their activities impose.** This could in some cases usefully include the (voluntary) support of the regulated body on which the costs fall. This support might in many cases be readily provided, even to the extent of figures being shared or even published.

5.2.1.3. The scale of intervention

218. The total resources allocated to specific programmes are of course ultimately decided at a higher level than the inspectors to whom we have spoken. And these decisions ultimately determine most of the fees charged to licensees and others, and the resource costs that the regulatory process will impose. **It would be useful to develop procedures that draw out a deeper, more critical assessment of the budgeting of**

[58] We understand that within ONR there is an internal "Economic challenge panel", but we have found no instance of its operation. We have also been advised that there is an established escalation route for a licensee to take such issues up with senior management including through the tier of level 4, 3, 2, 1 meetings. But this clearly failed to operate as well as it might have in the case of the EPR FCV.

some programmes that included more explicit regard to the costs imposed on industry. We appreciate that costs to regulated bodies are a factor already considered in such allocations, but our discussions suggest that this may not always be fully informed or monitored.

5.2.2. Developing and maintaining culture

5.2.2.1. The wider public interest

219. The culture of a competent safety regulator will necessarily focus on its specific role in society: the enforcement of safety regulations. The 'default' culture may however tend towards seeing the world in those terms alone, leaving it wholly to other institutions or individuals to look after other impacts of the regulator on social welfare.

220. The BEIS(BIS) statutory Regulators' Code and 'Duty to Have Regard to Growth' will have been issued to help ensure that regulators consider their economic impact on the businesses or sectors that they regulate. This current study is an element in ONR's response to these duties.

221. But there are of course other impacts of regulation on the public interest. In the nuclear safety context one of the more important may be the handling of very low radiation exposures. An international example, on which much has been written, is the international nuclear safety standards which determined Japanese civil evacuation policies after the Fukushima tsunami. The evacuations caused massive social disruption, and hundreds of deaths, which are widely believed to far exceed the harm likely to have been caused by the (avoided) radiation exposure (e.g. Murakami et al (2015), World Health Organisation (2016), World Nuclear Association (2016)). This is an extreme example, but it has been suggested to us by more than one experienced respondent that a more holistic view of policy and strategy by ONR would bring social benefits, without materially compromising nuclear safety.

222. It has also been suggested to us that the public fears of radiation may be reinforced by some nuclear safety regulators in a vicious circle, with the regulator responding to fears of low levels of radiation by confirming them. We have not delved into the effect of ONR on public and hence political perceptions of radiation. Our impression is that ONR also has not focused on this aspect of public perception, concerned as it is overwhelmingly with its ongoing inspectorate operations.[59] **There may be some merit to ONR reviewing the extent to which it sees itself as providing a public service concerned with <u>all</u> of its impacts on social welfare, including public awareness (by comparison perhaps with the CNSC – see paragraph 152 above), albeit with primary responsibilities for nuclear safety.**

[59] We note that, although R2P2 included some general information on radiation doses, provision of official information in this field seems today confined to Public Health England (e.g. Public Health England, 2011).

5.2.2.2. Promotion of enabling regulation

223. The enabling regulation initiative is courageous and having an impact. However the impact varies across programmes and individuals. We understand that new guidance is being prepared to develop a uniform perception of what it involves.

224. **It seems hard however to visualise the enabling regulation initiative being sustained in the long term without some carefully designed, continuing mechanism for obtaining frank and sometimes very specific feedback from regulated parties on its delivery**.

225. It is conspicuous that, despite the growth duty, enabling regulation **excludes** any explicit concern with costs or economic efficiency. And the efficiency gains at Sellafield are seen as a welcome but incidental by-product, rather than one material purpose of the initiative.

226. The current ONR culture of seeking to avoid consideration of costs makes it unrealistic to include any such consideration in enabling regulation at this stage. However **given the growth duty, and given that enabling regulation is about respecting the regulated body's concerns, it would seem anomalous for exclusion of cost recognition from enabling regulation to be maintained indefinitely.**

5.2.3. Developing analysis and strategic frameworks

5.2.3.1. Changing with the times

227. Over time technology and many other circumstances evolve and unforeseen special cases arise. Adaptation of safety regulation to such changes faces the obstacle that in safety regulation culture, worldwide, there is a ratchet. The culture is **deeply resistant to any change that can appear to reduce the stringency of its conventions for the specific hazard that it controls**.

228. Throughout this report we have touched on examples, raised by those with whom we have spoken, where existing regulations and standards (some UK-specific, others international) might have benefitted from adapting to circumstances. We noted above the inflexible application of the convention that, if an operating facility cannot be demonstrated to be within the 'broadly acceptable' risk zone of TOR, it should not operate. This is uncontentious in nearly all circumstances, but exceptions can arise. Another example where we see benefits from adapting to changing circumstances is in the attitude towards the mid-20th century "gross disproportion" case law on "reasonably practicable", on which the judiciary appears to be divided.

229. Progressive developments like TOR (especially) and R2P2, and the total restructuring at Sellafield, or the development of Enabling Regulation, are not common.

230. This conservatism is generally to be welcomed, but there is significant external perception of scope for review of aspects of the current regulatory framework. Some issues, such as ONR's information requirements and the development of resolution procedures for serious differences of view, are noted in this chapter. Other examples are listed in Appendix B.

231. As noted in section 5.1 and discussed in section 4.2.2, the framing of and weight given to the term "gross disproportion" in the ONR/HSE definition of ALARP is increasingly anomalous. Any change in such an area, even of emphasis, is culturally challenging. But finding language, such as ensuring "a margin of safety" that would be consistent with good practice in government appraisal methodology, and with the growth duty, could bring important benefits. It would in particular bring into clearer focus the role of uncertainty and the handling of non-monetised factors.

232. If such changes would be difficult to implement in the near-term, there are other steps that could improve things, for example: :

- Amend statements in ONR documentation that present gross disproportion as "the law". The law is "reasonable practicability" and gross disproportion is one (important, if now somewhat dated) precedent;
- Amend advice to inspectors that a court *would* seek 'gross disproportion'. It might, or it might not.

5.2.3.2. A role for economics

233. Economics is the core discipline in the economic regulation of natural monopolies. In other areas of regulation one of the more salient contributions of economics is to "cost-benefit analysis" (CBA) – in particular monetisation of the costs and benefits of regulatory options.

234. ONR rarely uses (or needs to use) CBA. It is in principle willing to consider CBAs presented by bodies that it is regulating. But we have been able to trace only one such case, and the importance of economic inputs into that CBA appear to have been minimal. But there is much more to applied microeconomics than CBA. (And there may sometimes be scope for economic input into the cost-*effectiveness* analysis of alternative ways to achieve a give safety improvement.)

235. We believe that ONR's economic impact would be improved by access to some quantitatively modest but high quality economic advice. An in-house economist might be too isolated. An external academic or consultancy source might be too far from the practical realities. But a suitable person, perhaps professionally associated with and sometimes working with the HSE economics team, could be worth considering. Such a post might help with advice on some specific cases and also contribute to issues such as framing the development of ALARP, contribute to ONR thinking on areas such as current discussions on global approaches to ALARP type issues, for example under the International Nuclear Regulators Association, and generally keep ONR in contact with developments in government appraisal methodology.

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Appendix A. Analytical and procedural conventions

This Appendix is in three parts.

Section B1 recounts an incident in which the very foundation of SFAIRP and non-prescriptive regulation came perilously close to being uprooted by the European Commission. It is a reminder that even the longest established conventions are not in the wider world sacrosanct. It also hints at the potential value of analytical depth, in understanding both the strengths and the limitations of whatever the current conventions may be, to help their evolution over time and to defend them effectively should the need arise.

Section B2 illustrates the kind of issue that are seen by external observers as either static or developing very slowly, that in more diverse professional environments (such as among operational researchers or economists in a public body) might be seen as worth debate to establish clearer understanding and perhaps further development.

Section B3 examines the current HSE/ONR rationale with respect to disproportionate costs, and how gross disproportion might be framed to align it, within the law, more closely to maximising the public interest.

A.1. The 2007 EC challenge

Debates around ALARP/SFAIRP and gross disproportion (GD) are UK centred. There is little that is close to ALARP in general health and safety law in other countries and, so far as we are aware, nothing similar to UK case law on gross disproportion. However the EC challenge on 2005 to the ALARP/SFAIRP principle (InfoCuria, 2007a) provides a sobering international context. The text of the European Court of Justice ruling (InfoCuria, 2007b) merits study by anyone wishing to see how that case failed in no small part because the Commission lawyers had not fully made their case. It also illustrates how the concept of balancing risk against cost did not fit into the Commission's mindset, and how the "grossly disproportionate" wording can sometimes, as here, be helpful.

The Health and Safety Commission published an internal document noting the outcome of the case from an administrative perspective (Health and Safety Commission, 2007). A short commentary from a legal perspective, in the journal Health and Safety at Work (2007), reports that the UK won its case only because of a weak legal team in the European Commission.[60] It was by no means clear cut.

It thus starkly illustrates the challenge of finding a conceptual framework and language for comparing costs with safety benefits that is both analytically defensible and politically acceptable.

[60] It appears that they did not see the significance of the final few words of Article 5(4) of the Directive, which says that it "shall not restrict the option of Member States to provide for the exclusion or the limitation of employers' responsibility where occurrences are due to […], or to exceptional events, the consequences of which could not have been avoided despite the exercise of all due care". The UK claimed that this legitimised SFAIRP.

The case also provides a counterbalance to concerns that over-literal interpretation of GD can lead to inefficiently costly regulation. The EC case was that the ALARP/SFAIRP regime was too *weak* in its formal requirements for spending on safety.[61]

A.2. Analytical and procedural development

The issues below are illustrations of the diverse issues, some big, some small, that might be taken as issues for debate, and from time to time review, in a culture that was focused on improvement of (as well as defence of) the status quo.

1. The concept and role of "international good practice": This appears to have been one element in problems faced by some of the GDA process. There are challenging issues here, in terms of, for example, "What exactly does such a concept mean?"; "To the extent that it has value, how can it best be absorbed?"; and "What does it imply for required ONR experience?". Substantial development of these issues could benefit from consultation in due course with reactor suppliers.

2. The role of industrial independent assurance: ONR has access to and makes use of the work of suppliers' independent safety assurance. Is there potential scope, if and when relationships of trust and respect are established, for more use of this function to reduce some regulatory burdens? (This we believe would be the suppliers' view.).

3. The risk-time issue: The convention that a facility cannot operate if it cannot rigorously demonstrate that the risk of a serious hazard falls below the upper tolerability limit is a sensible standard convention. But there will be special cases. The requirement, post Fukushima, that Dungeness B should be shut down for two months while initial new flood protection measures were introduced was probably not an economically efficient decision. The available information suggested that the risk was at worst close to the limit, but there was no adequate hard data. And the period in question was very short. This is a minor issue, but something that, in an outward looking analytical environment, might be seen as a convention to be refined.

4. The risk/cost balance in relevant good practice: Relevant good practice is universally recognised as a good basis, when it is possible, for establishing ALARP. But there appears to be no analysis of borderlines cases, where relevance may be deceptive or where good practice, while formally available, may occasionally not be the best way of achieving a given level of safety.

5. Corporate explanations of BSLs and BSOs: We have no independent view of the health impacts of radiation. The "linear no threshold" (LNT) assumption is widely applied, although there is evidence to suggest that it is likely to be conservative (World Nuclear Association, 2016c; Health Physics Society, 2007). In the absence of a precise alternative

[61] The Judgement records that "The Commission points to the fact that the assessment which must be made on the basis of the disputed clause [i.e. SFAIRP] involves account being taken of the cost of preventive measures, which clearly conflicts with the wording of the 13th recital in the preamble to Directive 89/391." However the relevant 13th recital text is recorded in the Judgement as saying merely that "... the improvement of workers' safety, hygiene and health at work is an objective which should not be subordinated to purely economic considerations". So that EC argument fell.

schedule of health impacts, reliance on LNT, as promoted in R2P2, remains the default. Current ONR guidance also explains the 20mSv annual limit for employees working with ionising radiation in terms of LNT. There may be merit in reflecting on such limits, and their underlying rationale.[62]

6. Public communication on low dose risks: There may be wider benefits to ONR presenting the evidence on risks associated with low radiation doses, and how it is used by the regulator, in a format more accessible to the wider public.

7. Societal risk terminology and handling: Early in the formative years of R2P2 HSE used the term 'societal risk' to mean accidents that caused multiple deaths. Sometimes fairly complex formulas were suggested to provide a multiplying factors increasing more than linearly with numbers of fatalities. This was widely criticised and HSE were persuaded to normally use the term 'societal concern'. ONR and HSE to their credit do not have any such multipliers. However the term societal risk is still around, with differing definitions. There is much potential for clarification of the several extra costs that arise from accidents that have substantial impacts beyond the workplace, and for discussion of how each can be handled. But this seems currently to be prevented by the blanket concept of gross disproportionality.

8. Updating the incorporation of GD into ALARP: This we discuss in the section B.3 below.

A.3. ALARP and GD

Section A.3.1 below comments, as background, on the 2006 Report of the House of Lords (HoL) Select Committee on Economic Affairs on the Management of Risk (House of Lords, 2006a) and on the Government (HSE) response. Section A.3.2. looks more closely at the interpretation and practical application of the 1949 case law.

A.3.1. The 2006 HoL Report and Government response

The HoL Committee recommended that "terms such as ALARP, Gross Disproportion and the Precautionary Principle should be more clearly defined or replaced with more specific and unambiguous requirements and concepts". We share the apparent view of HSE at that time that the Committee was not wholly on top of the issues. However the Government response, which to the best of our understanding sets out a considered HSE position that has not materially changed in many years, provides helpful context for our own review of the issues in section A.3.2.

The Government Response (House of Lords, 2006b) made many points, most of which are uncontroversial, but some do not wholly match our own findings.

Uncontroversial points, in the UK context, were as follows.

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[62] An alternative and perhaps more widely accepted explanation of the derivation of the ICRP 20 mSv limit is at Health Physics Society (2010).

- "Clarification to assist dutyholders is always worth considering, but more prescription is unlikely to be the answer."
- "There is still room for improvement in increasing the acceptability to industry [of ALARP, GD, TOR and PP] by better explanation and communication of their meaning and practical application"
- The vast majority of situations do not require explicit determination or even consideration of ALARP, GD etc., and in those cases where they are, reliance on relevant and established good practice normally suffices.
- Not everything can be captured by cost-benefit analysis (as conventionally defined).
- The Government does not have, and does not want to have, an algorithm or metric that can be applied in a mechanistic fashion – political and social judgments are a necessary and inevitable part of policy making and risk control.

The Response also says

"the frameworks allow for a balance to be struck between the multiple and disparate trade-offs between costs and benefits and other 'softer' socio-economic factors that occur in some cases". A balance does need to be struck. The point at issue is whether current practice *optimises* this balance.

"The Government's arguments for retaining the current frameworks based on ALARP, GD, TOR, etc. are that they have stood the test of time and are much envied and imitated the world over." There is truth in much of this, but the devil is in the detail. To the best of our knowledge no other country or international agency either envies or imitates GD.

The Response explains that GD is largely (or perhaps wholly) about "variations in the way that people and society value protection against different types of risks and different circumstances of exposure to these", drawing on factors such as those noted in item (v) in Section 4.1 of our main text, on incentives. These factors are important, but the use of apparently arbitrary "proportionality factors" may not be the best way to account for them.

It suggests that "It is a strength of this process that policy is adapted, guidance refined and increased clarity achieved on a case by case basis". But in practice we have found no evidence of refinement or clarity in the application of GD.

The Response also says that "All the frameworks are supported by clear public statements of Enforcement Policy in line with the principles of better regulation and an existing body of guidance and tools which promote consistent and balanced decision making in policy making and interventions". But we do not find that the current diverse approaches to GD always promote balanced decision making.

A.3.2. Case law and proportionality

HSE Guidance at the time of the HoL Report, and still current, reads as follows (HSE 2001b).

> "There is little guidance from the courts as to what reducing risks as low as is reasonably practicable means. The key case is Edwards v. The National Coal Board (1949), 1 All ER 743. In that case, the Court of Appeal considered whether or not it was reasonably practicable to make the roof and sides of a road in a mine secure. The Court of Appeal held that –

> *" ... in every case, it is the risk that has to be weighed against the measures necessary to eliminate the risk. The greater the risk, no doubt, the less will be the weight to be given to the factor of cost".* (Lord Justice Turner)

and

> *"'Reasonably practicable' is a narrower term than 'physically possible' and seems to me to imply that a computation must be made by the owner in which the quantum of risk is placed on one scale and the sacrifice involved in the measures necessary for averting the risk (whether in money, time or trouble) is placed in the other, and that, if it be shown that there is a gross disproportion between them – the risk being insignificant in relation to the sacrifice - the defendants discharge the onus on them."* (Lord Justice Asquith)

The Courts will look at all the relevant circumstances of the particular case when reaching decisions."

As we note in section 4.2.2.1, Asquith LJ, in talking about proportionality of "the sacrifice involved [by the owner]… in the measures necessary for averting the risk", was clearly referring to sacrifice by the employer, relative to 1949 perceptions of what is now described as "the value of a prevented fatality".

Professor Andrew Evans, a leading transport safety expert long familiar with HSE conventions (Evans 2013), has discussed this as follows, albeit in the context of transport safety, which is much more amenable to formal cost benefit analysis than nuclear safety.

> "At first sight [Asquith LJ's comment] seems to be an early and admirable demand for safety cost benefit analysis, and so it is. The problem lies in the phrase "gross disproportion", because it seems to require that the safety benefit:cost ratio (BCR) should be much less than 1 before the law is satisfied. However, that was reasonable in 1949, because there were then no formal valuations of the prevention of fatalities and injuries, and the only financial figures relating to casualties were compensation payments to victims and their relatives. These were low. In particular, in the case in question the compensation paid to the widow of the coal miner after his death was £984, equivalent to about £27,000 at 2009 prices. It is reasonable to suppose that the Court had that figure in mind when specifying the requirement for gross disproportion."

The term was picked up in the Health and Safety at Work etc. Act 1974. By the early 1970s there were established social valuations of the risks of *transport* injuries and fatalities. But even if the HSE, in steering this legislation, was aware if this development, the values were in real terms far below those prevailing in the late 1970s which were even further below those prevailing in the late 1980s, following successive developments in methodology.

Evans (2013) continues in measured terms as follows:

> "Since the legal case in 1949, …valuations for the prevention of fatalities (VPF) and injuries (VPI) have been developed. These are much higher than the 1949 compensation payments; for example, the 2009 British official VPF, based on willingness-to-pay (WTP), was £1.59 million, or about 60 times greater in real terms than the 1949 compensation. Therefore there would now seem to be no need for gross disproportion between the WTP-based benefits of safety measures and their costs. However, the problem for today is that while current VPFs are drastically higher than compensation levels in 1949, there has been no corresponding change in the legal phraseology. Therefore the law still seems to require safety BCRs to be much less than 1, even with today's VPFs. The current British railway safety regulator, the Office of Rail Regulation (ORR), says that if Parliament had intended a different test, it would have used different wording in the HSWA 1974 (ORR, 2008).[63]

[63] This ORR argument is hard take seriously as there was no satisfactory alternative available in 1974.

> The problem is exacerbated by uncertainty about exactly what the law does require. Nobody wishes to break the law, especially on safety. That encourages decision-makers and lawyers to be cautious and adopt safety measures for which the BCR may be well below 1."

Transport safety differs from nuclear safety insofar as many of the impacts of a change in safety level can now often be reliability monetised. Perhaps for that reason they are not always given excessive weight.[64]

In the nuclear context the 'external' commercial and political impacts of a major nuclear accident, or near-miss, and the diversity of the impacts of a major release of fission products, far exceed those of any readily imaginable railway accident. However more recently it has become more clearly accepted in UK government that many policy decisions entail important non-monetised factors, that may even swamp most others. It seems unlikely that Asquith LJ had in mind any such factors in the context of the National Coal Board in 1949. But clearly, for some kinds of nuclear accident or incident, there are major factors of this kind.

It is now widely accepted that analytical support for policy decision making must consider and present important non-monetised impacts alongside any monetised costs and benefits. Judgment is then needed. But, as we note in section 4.2.2.1, this is not helped by the terminology of gross disproportion or by arbitrary factors by which to multiply monetised impacts. Indeed these have the flavour of an "algorithm or metric that can be applied in a mechanistic fashion", which the HSE and ONR rightly deplore.

The more reasoned approach of assessing monetised and non-monetised costs and benefits and then taking a proportionate approach to their comparison is the UK government norm. The 1949 case law has to be recognised and modern regulations should not be inconsistent with its sensible interpretation. But it is hard to justify, especially since the late 1980s when modern levels of risk valuation were largely established, continuation of formal interpretation of that case law and of SFAIRP in a way that departs so very substantially from serving the public interest.

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[64] This was notable when HSE was the railways safety regulator and developing the case against implementing a recommendation of the joint Southall and Ladbroke Grove Inquiry that a specific, very costly system should be installed to virtually eliminate "signals passed at danger" on British railways. A much less costly option, which achieved slightly less risk reduction, was adopted instead, following much analysis. In addressing this trade-off the concept of GD was never considered.

As Evans notes, the railway safety regulator (now the Office of Rail and Road) would not challenge the GD concept. However soon after railway safety regulation was transferred from HSE the industry's Rail Safety and Standards Board (2006, page 3), in a Discussion Paper no longer on the web, recorded the common view of experts outside HSE/ONR that: "If we have correctly weighed the safety benefits […] there can be no justification for demanding that duty-holders take action disproportionate to its benefits[…]."

In other transport modes the issue of disproportionality does not arise.

Appendix B. Enabling Regulation principles

This Appendix reproduces Appendix 4 of ONR General Inspection Guide (ONR, 2016).

ENABLING REGULATION

Definition: 'A collaborative approach with duty-holders and other relevant stakeholders that seeks effective delivery against clear and prioritised safety (including nuclear safety, transport, conventional health and safety) and security outcomes.'

Key Principles:

'Collaboration' – it is recognised that this can lead to accusations that we are 'too close to industry'. This is not the case. Collaborate does not mean compromise, but rather it requires regulators, duty-holders as well as other stakeholders (e.g. DECC, NDA) to focus on a common overall objective and work together to achieve the desired outcome.

Communication – we need to have agreed priorities and real trust between all stakeholders being clear about the outcomes we are seeking to achieve. It also means being very clear with other stakeholders, for example the public, about how we have made our regulatory decisions and the factors we considered when arriving at those decisions.

Independence – Although we may adopt a multi agency approach (e.g. Sellafield G6) in terms of collaboration with stakeholders on agreed activities, we must nevertheless retain a clear and transparent process, independent of this, when making our regulatory decisions.

Outcome focussed – Often we can get drawn into details and process issues with dutyholders that can generate diversions and distractions. We need to keep focussed on the outcome we are trying to achieve, considering all relevant factors and acting proportionately, to avoid this.

Pragmatic – In order to achieve some outcomes, it may be appropriate in some circumstances to accept a less than ideal solution. 80% right today is very often preferable to 100% right in the distant future.

Risk appetite – There are risks with operating in this way, for example a perception that we are working too close to industry; this could severely damage our reputation. We need to be clear that we understand the risks involved, but actively manage them and articulate to stakeholders why we are taking this course of action. It is important that ONR senior management/board accepts any risks being taken and is prepared to fully support those undertaking the work if the risk should materialise.

Strong internal governance and robust assurance – it is essential that we and duty-holders have strong and effective governance structures that are open and transparent; it is critical that ONR's decision making continues to be demonstrably robust and that appropriate assurance processes are in place.

Avoid passive acceptance – seek fit-for-purpose solutions – we can contribute to an unhelpful outcome by passively accepting duty-holders' proposals. This does not mean we tell duty-holders what to do, but we should challenge their proposals if we think that solutions they are proposing are disproportionate to the problems they seek to overcome. "Goldplating", leading to delays in safety benefits being realised or sub-optimal use of scarce resource, especially in the public sector in times of austerity, is not desirable.

Appendix C. International comparisons

C.1. United States of America

In the U.S.A., *regulatory analysis* is required in connection with any "significant regulatory actions."[81] Not all such "regulatory analysis," however, includes benefit-cost analysis. *Whether* a "regulatory analysis" by the U.S. Nuclear Regulatory Commission (NRC) should include some formal evaluation of benefits (also referred to as "values") and costs (also referred to as "impacts"), and if so, *how* those benefits and costs should be evaluated, is currently governed primarily by two documents: the NRC's Regulatory Analysis Technical Evaluation Handbook (the *Handbook)*,[82] and the NRC's Regulatory Analysis Guidelines (the *Guidelines*).[83]

Broadly speaking, regulatory actions that concern nuclear power facilities may or may not involve a "backfit." Federal regulations define "backfitting" in pertinent part as "the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility" as a result of new NRC regulations or new interpretations of existing regulations. [84] The "backfit rule"[85] requires that (subject to some important exceptions, noted below) regulatory actions falling within its scope be supported by a regulatory analysis that incorporates benefit-cost analysis. For non-backfit regulatory actions, there is no statute or NRC regulation specifically requiring that a regulatory analysis be performed, but the NRC's position is that such an analysis should be conducted.[86] The benefit-cost element of such an analysis would be much the same whether the proposed regulation fell within or outside the backfit rule.[87]

The *Guidelines* provide relatively high-level guidance as to whether a proposed regulatory change (backfit or otherwise) should proceed to the analysis stage, whether that analysis

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81 Executive Office of the President, "Federal Regulation," Executive Order 12291, Federal Register, Vol. 46, No. 32, pp. 13193–13198, February 19, 1981, http://www.archives.gov/federal_register/codification/executive_order/12291.html; Executive Office of the President, "Regulatory Planning and Review," Executive Order 12866, Federal Register, Vol. 58, No. 190, pp. 51735–51744, October 4, 1993, http://www.archives.gov/federal_register/executive_orders/pdf/12866.pdf. Note that the U.S. NRC is an independent, rather than executive, agency and is not formally bound by the terms of executive orders although it has committed to act consistently with the terms of these orders.

82 NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook," January 1997, http://pbadupws.nrc.gov/docs/ML1112/ML111290858.pdf.

83 NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," September 2004, http://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0058/br0058r4.pdf.

84 10 CFR §50.109, http://www.nrc.gov/reading-rm/doc-collections/cfr/part050/part050-0109.html.

85 10 CFR §50.109, http://www.nrc.gov/reading-rm/doc-collections/cfr/part050/part050-0109.html.

86 Policy Issue (Notation Vote) to the Commissioners from R.W. Borchardt, "SECY-12-0110—Consideration of Economic Consequences within the U.S. Nuclear Regulatory Commission's Regulatory Framework," dated August 14, 2012, Enclosure 5 (noting that the NRC chooses to comply with the provisions of Executive Order 12291 and Office of Management and Budget Circular A-4), www.nrc.gov/reading-rm/doc-collections/commission/secys/2012/2012-0110scy.pdf.

87 *Guidelines* at §1, note 2; Enclosure 5 to SECY-12-0110 dated August 14, 2012.

should include evaluation of values and impacts, and what such an evaluation should include. In terms of the supporting regulatory analysis, the most significant distinction between backfits and other regulatory actions is that the NRC can require backfitting of a facility "only when it determines…that there is a *substantial increase* in the overall protection of the public health and safety or the common defense and security to be derived from the backfit..."[88] Regulatory actions falling outside the backfit rule do not require a showing of substantial increase in overall protection.[89] The backfit rule's requirement "that the direct and indirect costs of implementation for that facility are justified in view of this increased protection," is understood to mean a benefit-cost analysis essentially the same as would be required in a non-backfit situation.

The *Guidelines* identify various categories of values and impacts (that is, benefits and costs) that should be considered in a regulatory or backfit analysis:

"Values	The beneficial aspects anticipated from a proposed regulatory action such as, but not limited to, the (1) enhancement of health and safety, (2) protection of the natural environment, (3) promotion of the efficient functioning of the economy and private markets, and (4) elimination or reduction of discrimination or bias.
Impacts	The costs anticipated from a proposed regulatory action such as, but not limited to, the (1) direct costs to the NRC and Agreement States in administering the proposed action and to licensees and others in complying with the proposed action, (2) adverse effects on health, safety, and the natural environment, and (3) adverse effects on the efficient functioning of the economy or private markets."[90]

The *Guidelines* suggest that to the extent practicable, the benefit-cost analysis be fairly granular. The *Guidelines* identify various categories of stakeholders potentially affected by the proposed regulations, including "the general public; units of State and local government; Indian tribes; licensees of the NRC and/or Agreement States; employees of licensees, contractors, and vendors; the NRC; and other Federal agencies." The regulatory analysis should ideally identify and value costs and benefits by stakeholder category; impacts should be calculated by year for each year that stakeholders will be affected by the proposed action; calculations should be performed and results expressed where possible in monetary terms; and calculations should be performed in constant dollars and discounted to present value. The *Guidelines* and *Handbook* provide a specific, recommended value (expressed in dollars

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88 10 CFR §50.109, http://www.nrc.gov/reading-rm/doc-collections/cfr/part050/part050-0109.html.

89 A discussion of the "substantial additional protection" criterion is beyond the scope of this paper, but the *Guidelines* identify one approach to quantitative analysis of the significance of a proposed regulation: measurement of the extent to which the regulation would change a facility's "core damage frequency," as well as the likely effectiveness of containment measures to mitigate harm. *Guidelines* at §3.3.1. The analysis provides a basis for determining when a proposed regulation should proceed to formal regulatory analysis, when the proposed regulation should *not* be considered further, and when the exercise of judgment by management is called for.

90 *Guidelines* at §4.3. These definitions also appear in the *Handbook* at § 4.3.

per person-rem) for exposure to radiation to be used in performing the calculations.[91] The results should be displayed primarily in absolute terms rather than in ratios of values to impacts.[92]

The *Guidelines* specify that "[v]alue and impact estimates are to be incremental best estimates relative to the baseline case, which is normally the no action alternative." The "no action" alternative is not necessarily the same as the status quo. With uncertainty surrounding how the future will unfold in the absence of the proposed action, consideration of costs and benefits relative to multiple baseline cases may be appropriate.[93]

The *Guidelines* also suggest a number of specific items (value and impact "attributes") that should be assessed for each regulatory alternative[94] being evaluated:

	Value (Benefit) Attributes	Impact (Cost) Attributes
	• reductions in public and occupational radiation exposure • enhancements to health, safety, or the natural environment • averted onsite impacts • averted offsite property damage • savings to licensees • savings to the NRC • savings to State, local, or tribal governments • improved plant availability • promotion of the efficient functioning of the economy • reductions in safeguards risks	• costs to licensees • costs to the NRC • costs to State, local, or tribal governments • adverse effects on health, safety, or the natural environment • adverse effects on regulatory efficiency or scientific knowledge needed for regulatory purposes • adverse effects on the efficient functioning of the economy and private markets

91 *Guidelines* at §§4.3, 4.3.5. At the time of the 2004 *Guidelines*, the value was $2,000 per person-rem. This number was originally calculated in 2005 as the product of $3 million, the then-current value of a statistical life, and the risk coefficient for stochastic health effects (7.3 x 10-4 per person-rem), rounded to the nearest $1,000. In 2010, however, the Office of Nuclear Reactor Regulation began the process of reevaluating the appropriate dollar per person-rem conversion factor. That process led to the publication in August 2015 of a Draft Report for Comment, "Reassessment of NRC's Dollar Per Person-Rem Conversion Factor Policy," NUREG-1530 Rev. 1, http://www.nrc.gov/docs/ML1523/ML15237A211.pdf. The Draft Report proposes five revisions to the conversion factor and the approach used to arrive at it: "First, it updates the dollar per person-rem conversion factor to $5,100 per person-rem. The value is based on an updated value of a statistical life of $9.0 million and a nominal risk coefficient factor of 5.7 x 10-4 per person-rem. Second, it uses low and high estimates of a statistical life value instead of a single value. Third, it directs the staff to round the conversion factor to two significant figures instead of simply rounding to the nearest $1,000 value. Fourth, it establishes a method for keeping the dollar per person-rem conversion factor current. Finally, it provides guidance to the staff on when to use a higher dollar per person-rem conversion factor." http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1530/r1/. The period for commenting on the Draft Report has now closed, but no further action on this issue appears to have taken place.

92 *Guidelines* at §4.4.

93 *Guidelines* at §4.3.

94 Although not discussed here, the NRC's regulatory analysis methodology anticipates that *alternative* approaches to resolving problems will be identified and subject to analysis, including benefit-cost analysis. See, e.g., *Handbook* at § 4.2.

A more detailed checklist of potential attributes, and a discussion of each (including specific quantification methodologies for particular attributes), can be found in the *Handbook.*[95]

The backfit rule itself includes a non-exhaustive list of information items that should be included in the regulatory analysis,[96] and the *Handbook* more explicitly links a number of these to the benefit-cost component of the regulatory analysis.[97] For the most part, these requirements are differently worded versions of the items listed in the table above.

One important set of considerations in the quantification of values and impacts is the treatment of uncertainty. The *Handbook's* discussion of Value-Impact Analysis includes a fairly detailed discussion of types of uncertainty and the techniques for addressing them, such as Probabilistic Risk Assessment (PRA).[98] The *Guidebook* and *Handbook* recommend that PRA techniques be used where feasible in arriving at "best estimates" of values and impacts. Certain attributes should normally be calculated by using PRAs to estimate their expected (probability-weighted) values: public health, occupational health, offsite property and onsite property.[99]

As noted above, the backfit rule does include some exceptions. Most importantly, no formal regulatory analysis is required where "regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security."[100] The *Guidelines* explain that "[t]he level of protection constituting "adequate protection" is that level which must be assured without regard to cost," determined on a case-by-case basis.[101] "Adequate protection" is not formally defined in the backfit rule itself or in the *Guidelines*.[102]

Regulatory proposals that would *relax* safety requirements are not subject to the backfit rule, but nonetheless require consideration of values and impacts. The *Guidelines* recommend that such proposals be supported by a demonstration that two conditions are satisfied: "(1) The public health and safety and the common defense and security would continue to be adequately protected if the proposed reduction in requirements or positions were

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[95] *Handbook* at §§5.5 (Identification of Attributes), Table 5.1 (Checklist for identification of affected attributes), 5.7 (Quantification of Attributes).

[96] 10 CFR §50.109(c).

[97] *Handbook* at §2.2, Table 2.2, "Checklist for specific backfit regulatory analysis requirements."

[98] *Handbook* at §5.4.

[99] *Guidelines* at §§3.2, 4.3; *Handbook* at §§4.3, 5.7.

[100] 10 CFR §50.109(a)(4)(ii).

[101] *Guidelines* at §2.3, note 7. *Handbook,* §2.2.

[102] In 1986, the NRC issued a "Policy Statement concerning Safety Goals for the operations of Nuclear Power Plants," but these safety goals play no explicit role in the "adequate protection" analysis. The *Guidelines* clarify that the risk levels identified in the Policy Statement represent a lower standard than "adequate protection," and should be used only as "a reference point in ascertaining the need for safety enhancements." NRC, "Policy Statement on Safety Goals for the Operation of Nuclear Power Plants," August 4, 1986. Corrected and reprinted at Federal Register, Vol. 51, No. 162, pp. 30028–30035, August 21, 1986, www.nrc.gov/reading-rm/doc-collections/commission/policy/51fr30028.pdf; *Guidelines* at §§3.1, 3.3

implemented. (2) The cost savings attributed to the action would be substantial enough to justify taking the action."[103]

Post-Fukushima

In the aftermath of the accident at the Fukushima Dai-ichi nuclear plant in Japan, the NRC re-evaluated the adequacy of its regulatory framework for considering the economic consequences of an unintended release of radiation to the environment, particularly offsite property damage. The NRC's staff concluded that the existing regulatory framework (e.g., the *Guidelines* and *Handbook*) were sound and sufficiently flexible to address offsite economic consequences. (Impacts to offsite property are, as noted above, already included in the attributes for which values and impacts are to be evaluated in a standard regulatory or backfill analysis.)

However, in August 2012, the NRC's Executive Director for Operations (EDO) proposed a number of alternative ways in which the existing regime might be improved notwithstanding the staff's conclusion that existence guidance was sound. EDO's Option 2, "Enhanced Consistency of Regulatory Analysis Guidance," would seek to more "systematically update and enhance regulatory analysis guidance in a more comprehensive, integrated, and coordinated fashion" compared to the status quo. Guidance for estimating offsite economic consequences would also be improved using more current data, and more advanced modelling. This option would also seek to harmonize the approach to analysis across the agency (e.g., by making regulatory, backfill, and environmental analyses more consistent in their treatment of economic consequences, and by making the analyses more consistent across "lines of business"). The EDO noted that two items relevant to the estimation of economic consequences—how replacement energy costs should be modelled, and the appropriate conversion factor for exposure to radiation (expressed in dollars per person-rem)—were already being studied, and would ultimately result in changes to the guidance documents.[104] In March 2013, the NRC approved Option 2.[105] The EDO submitted an implementation plan for moving forward with Option 2 (now referred to as a "Regulatory Gap Analysis"), the updates to existing guidance concerning replacement energy costs and conversion factor for human exposure to radiation, and other pending initiatives, on January 2, 2014.[106]

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[103] *Guidelines* at §2.2; see also *Handbook* at § 2.6.

[104] SECY-12-0110 Policy Issue (Notation Vote) dated August 14, 2012, *supra* note 86. The *Guidelines* call for a conversion factor of $2,000 per person-rem. The original conversion factor, developed in the 1970s, was $1,000 per person-rem and in the 1980s the NRC characterized the factor as capturing not only the monetary value of health impacts, but offsite property damage as well. The current conversion factor (and any updated factor emerging from the initiative now in progress to adjust it) is intended to capture only health impacts; offsite property damage must today be evaluated separately, and this will continue to be the case. SECY-12-0110 Policy Issue (Notation Vote) dated August 14, 2012, *supra* note 86, at Enclosures 7 and 8.

[105] Memorandum to R.W. Borchardt from the U.S. NRC, "Staff Requirements – SECY-12-0110 – Consideration of Economic Consequences within the U.S. Nuclear Regulatory Commission's Regulatory Framework," dated March 20, 2013, www.nrc.gov/docs/ML1307/ML13079A055.pdf.

[106] Policy Issue Information, SECY-14-0002, "Plan for Updating the U.S. Nuclear Regulatory Commission's Cost-Benefit Guidance," January 2, 2014, www.nrc.gov/reading-rm/doc-collections/commission/secys/2014/2014-0002scy.pdf

As of the time that this report is being finalized, the *Guidelines* and *Handbook* continue to be the most definitive statements about when and how benefit-cost analysis is to be performed (although they are not the only guidance documents that may contain relevant information), and while those documents are expected to be revised, benefit-cost evaluation is unlikely to lose its prominence in the broader regulatory analysis process.

C.2. Canada

Nuclear facilities in Canada are regulated by the Canadian Nuclear Safety Commission (CNSC). The CNSC's most formal statement of policy concerning the use of cost-benefit information is Regulatory Policy P-242, "Considering Cost-Benefit Information," dated October 2000.[107] P-242 states that the CNSC's policy is that:

- "When conducting a proceeding for purposes of a decision under the *Nuclear Safety and Control Act* that involves a licence or an order, the Commission or its designated officers will consider relevant information on costs or benefits that is submitted by a person who is participating in the process.

- When conducting consultations on a draft regulatory standard or a draft regulatory policy, the Commission will take into account, when fixing the deadline for submission of comments, the time that may be required for the preparation of submissions on the costs and benefits related to the proposed standard or policy.

- When receiving or considering any relevant information on costs or benefits that is submitted in relation to a decision involving a licence or order, the Commission or its designated officers will be governed by the following principles:
    - Information on costs and benefits is only one factor that may be considered in making 'regulatory decisions' or taking 'regulatory actions' under the Act, and does not displace legal requirements and other valid regulatory considerations.
    - The information on costs or benefits may be quantitative or qualitative in nature.
    - Consideration of the information on costs or benefits may be quantitative or qualitative in nature."

The CNSC is currently considering updating this policy, and has published a "discussion paper" called "How the CNSC Considers Information on Costs and Benefits: Opportunities to Improve Guidance and Clarity."[108] The discussion paper appears to present the Commission's current thinking concerning the role that cost-benefit information does and should play in regulatory decision-making. A period for stakeholders to comment on the discussion paper closed in August 2016, and the CNSC plans to post a "What We Heard

[107] CNSC Regulatory Policy P-242, Considering Cost-Benefit Information, October 2000, http://www.nuclearsafety.gc.ca/pubs_catalogue/uploads/P-242_e.pdf.

[108] CNSC Discussion Paper DIS-16-01, "How the CNSC Considers Information on Costs and Benefits: Opportunities to Improve Guidance and Clarity," http://nuclearsafety.gc.ca/eng/acts-and-regulations/consultation/comment/d-16-01/index.cfm, at §1.

Report" in the near future. The rest of this discussion will highlight the major observations of interest arising from the policy, the discussion paper, and the comments submitted by industry.

Policy P-242 speaks of the agency considering "relevant information on costs or benefits that is submitted by a person who is participating in the process." The policy (both as worded and as characterized in the discussion paper) appears, as various industry commenters noted, to place the burden of submitting cost-benefit information on the industry rather than the agency. The discussion paper is fairly explicit that submission of this information is voluntary and that the CNSC does not propose creating a new obligation: "The NSCA [Nuclear Safety and Control Act] and its regulations do not explicitly require submission of cost-benefit information to the CNSC. This discussion paper does not propose any new legal requirements for licensees and applicants."[109]

The industry expressed concern that despite the importance and value of cost-benefit evaluations, the CNSC was not committing to meet any particular standard in its analysis of cost-benefit information. Ontario Power Generation and Bruce Power both commented, "While this paper offers welcome flexibility on how licensees can calculate & submit cost-benefit implications, it does not fully recognize the CNSC's own responsibility to gather, analyze and disclose this type of information."[110]

It is not entirely clear that the CNSC perceives *itself* as obligated to perform or require a cost-benefit evaluation in connection with regulations or regulatory documents, or what it understands to be the scope or depth of any cost-benefit analysis that it must conduct. The CNSC appears to recognize some level of obligation to analyze costs and impacts of new or amended regulations, and to present its results in a Regulatory Impact Analysis Statement (RIAS). The CNSC similarly notes that in July 2015 it "began including impact statements along with draft regulatory documents being issued for consultation" ("regulatory documents" being guidance documents as opposed to actual regulations).[111] However, some industry commenters noted that the CNSC does not say *how* it will perform its RIASs, and objected to what they viewed as superficial analyses performed by the CNSC in the past. They called for the agency to spell out its own obligations more explicitly, and suggested that the agency act more consistently with other government policies and guidelines such as The Canadian Cost-Benefit Analysis Guide.[112] One commenter viewed the CNSC as "elevating the role of the

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[109] CNSC Discussion Paper DIS-16-01, "How the CNSC Considers Information on Costs and Benefits: Opportunities to Improve Guidance and Clarity," http://nuclearsafety.gc.ca/eng/acts-and-regulations/consultation/comment/d-16-01/index.cfm, at §2.3.

[110] Comments of Ontario Power Generation, http://www.nuclearsafety.gc.ca/eng/pdfs/DIS/16-01/DIS-16-01-Comment-Received-OPG.pdf and Bruce Power, http://www.nuclearsafety.gc.ca/eng/pdfs/DIS/16-01/DIS-16-01-Comment-Received-Bruce-Power-.pdf. The Canadian Nuclear Association submitted a similar comment. http://www.nuclearsafety.gc.ca/eng/pdfs/DIS/16-01/DIS-16-01-Comment-Received-CNA.pdf.

[111] CNSC Discussion Paper DIS-16-01 at §§3.1, 3.3.

[112] Ontario Power Generation and Bruce Power comments, citing Treasury Board Canada Secretariat , "Canadian Cost-Benefit Analysis Guide: Regulatory Proposals," http://www.tbs-sct.gc.ca/hgw-cgf/finances/rgs-erdg/wwad-cqnf/col/analys/analys-eng.pdf; the "One-for-One Rule," https://www.tbs-sct.gc.ca/hgw-cgf/priorities-priorites/rtrap-parfa/araofor-raarupu-eng.asp; and "The Cabinet Directive on Streamlining Regulation," http://publications.gc.ca/collections/Collection/BT22-110-2007E.pdf.

CBA to a licensing requirement and putting the onus on licensees to prove cost-benefit information or to complete a CBA for a wide range of submissions." While Policy P-242 does not require the submission of cost-benefit information, "the Discussion Paper implies CNSC may begin requesting and possibly mandating cost-benefit information from licensees."[113]

Although submission of cost-benefit information is optional, the CNSC encourages parties to provide it. "CNSC impact statements now explicitly request feedback from stakeholders on the alternatives, costs and other potential impacts associated with new or recently amended draft regulatory documents."[114] CNSC is amenable to a range of possible cost-benefit methodologies, including "formal, comprehensive approaches, such as the production of cost-benefit analyses (CBA), cost-effectiveness analyses (CEA), and multi-criteria decision analyses (MCDA)."[115] MCDA is "similar to traditional cost-benefit analysis; however it does not use dollar value as an equalizer to compare different aspects of the alternatives under consideration. This can be useful in situations where it may be challenging to evaluate considerations in monetary terms; e.g., ecological impacts or quality of life."[116] Some industry commenters believed, however, that the agency did not allow adequate time for licensees to prepare cost-benefit analyses or consider alternative solutions, and proposed that time be allotted to prepare such analyses *before* proposed regulatory actions were issued for public review, rather than after.[117]

Cost-benefit analysis is not dispositive in the CNSC's decision-making process. Canada is a "safety first" regime. As explained by the discussion paper, "The CNSC makes a wide variety of decisions, so the role of cost-benefit information in any specific decision also varies and depends on many factors. However, in all cases, costs and benefits are only one consideration that the CNSC may take into account when making a decision, and this is always done in a manner that puts safety first."[118] This philosophy is reflected in the CNSC's requirement that its licensees implement measures to keep radiation doses received by workers and members of the public as low as reasonably achievable (ALARA). The evaluation of costs and benefits is viewed as helpful to the ALARA analysis, but not determinative: "In implementing the ALARA principle, it must be determined whether the efforts to reduce doses are worthwhile. Some problems may be resolved using cost-benefit analysis or other quantitative techniques. However, it may be inappropriate to solely consider quantitative arguments in judging reasonableness." Qualities that the CNSC calls

[113] Comments of Cameco Corporation, http://www.nuclearsafety.gc.ca/eng/pdfs/DIS/16-01/DIS-16-01-Comment-Received-Cameco-Corporations.pdf.

[114] CNSC Discussion Paper DIS-16-01 at §1.

[115] CNSC Discussion Paper DIS-16-01 at §2.2.

[116] CNSC Discussion Paper DIS-16-01 at §2.6.3.

[117] Ontario Power Generation and Bruce Power comments; comments of Canadian Nuclear Association, http://www.nuclearsafety.gc.ca/eng/pdfs/DIS/16-01/DIS-16-01-Comment-Received-CNA.pdf.

[118] CNSC Discussion Paper DIS-16-01 at §1.

"understanding, good practice and feasibility" are said to help judge reasonableness, with the weighing of costs against benefits identified as a possible component of "feasibility."[119]

And while there may be no formal requirements specifically applicable to the agency's evaluation of cost-benefit information, the CNSC notes that many of its "complex decisions… are guided by a formal process for risk-informed decision-making (RIDM), which takes into account costs and benefits after a risk assessment has occurred." The CNSC notes some of the situations in which cost-benefit analysis has been effectively employed, such as when choosing between two or more alternative approaches to addressing a particular safety objective,[120] evaluating alternative approaches to issues identified during a Periodic Safety Review of a nuclear plant,[121] or identifying the "best available technology economically achievable (BATEA)."[122]

The "guidance" provided by the CNSC concerning the submission of cost-benefit information is considerably less specific than even the U.S. NRC's *Guidelines* document. The CNSC identifies a variety of elements that should ideally be included in a cost-benefit analysis, but does not go much beyond listing them and observing that they may be important. The list of elements includes: a statement of rationale for the project; identification of alternatives; forecasts of impacts; uncertainty analysis; sensitivity analysis; and the choice of appropriate discount rate.[123]

C.3. OECD and the OECD Nuclear Energy Agency

The Organisation for Economic Co-Operation and Development (OECD) has written and sponsored numerous publications and workshops focusing on regulatory policy as a tool for promoting social welfare and economic prosperity. The OECD is a proponent of Regulatory Impact Analysis (RIA), which it describes as "a systemic approach to critically assessing the positive and negative effects of proposed and existing regulations and non-regulatory alternatives. As employed in OECD countries, it encompasses a range of methods. It is an important element of an evidence-based approach to policy making."[124] The OECD has described cost-benefit analysis as "the core method of RIA."[125] Many member-states of the OECD which are relative newcomers to the commercial nuclear sector make use of RIA rather than an indigenous approach.

The OECD's Nuclear Energy Agency (NEA), however, has not formally endorsed any particular form of RIA or cost-benefit analysis in its own publications and policy statements

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[119] CNSC Regulatory Guide G-129, Keeping Radiation Exposure and Doses "As Low as Reasonably Achievable (ALARA)," October 2004, http://www.nuclearsafety.gc.ca/pubs_catalogue/uploads/G129rev1_e.pdf.

[120] CNSC Discussion Paper DIS-16-01 at §2.5.

[121] CNSC Discussion Paper DIS-16-01 at §2.6.4.

[122] CNSC Discussion Paper DIS-16-01 at §2.6.5.

[123] CNSC Discussion Paper DIS-16-01 at §4.3.

[124] OECD web page, http://www.oecd.org/gov/regulatory-policy/ria.htm.

[125] Deighton-Smith, R., A. Erbacci and C. Kauffmann (2016), "Promoting inclusive growth through better regulation: The role of regulatory impact assessment," *OECD Regulatory Policy Working Papers*, No. 3, OECD Publishing, Paris. http://dx.doi.org/10.1787/5jm3tqwqp1vj-en, at 6, 9.

concerning the regulation of the nuclear industry. For example, in a 2011 publication, "Improving Nuclear Regulation," the NEA discussed the issue of regulatory requirements related to backfitting. It observed that once a safety issue had been identified, "some regulators may use a largely qualitative approach, considering such factors as the degree of improved safety, improved public confidence, or other factors" while "other regulators may choose to use a more quantitative approach," e.g., one incorporating cost-justification, to judging backfits.[126] But the NEA did not recommend one approach over another. As it stated in an earlier document:

Nuclear safety regulators generally require that their basic level of protection criterion (e.g., "no unreasonable risk")[127] must be met regardless of cost or other considerations. When considering safety improvements beyond that level, there may come a point where a safety improvement may not be rationally justified after evaluating offsetting factors such as costs, worker radiation exposure, worker safety and equipment degradation through excessive testing. For this reason, the regulatory body's integrated framework for decision making may include provision for considering these types of trade-offs. Whether this provision includes a formal quantitative cost-benefit methodology or a qualitative consideration of trade-offs is a policy matter for each regulatory body.[128]

The NEA generally encourages nuclear regulators to be consistent, transparent, and evidence-based in their decision-making,[129] but does not take a position on whether nuclear regulations should, as a general proposition, reflect a formal weighing of costs against benefits. Rather, the NEA acknowledges the pros and cons of different regulatory approaches (e.g., the "prescriptive," the "case- and facilities-based," the "outcome-based," the "risk-informed and hazard-informed," and the "process-based," among others).[130]

[126] Nuclear Energy Agency, "Improving Nuclear Regulation: NEA Regulatory Guidance Booklets, Volumes 1-14," 2011, http://www.oecd-nea.org/nsd/docs/2011/cnra-r2011-10.pdf, at 75-76.

[127] "No unreasonable risk" is one of the different criteria for the basic level of protection in OECD countries identified by the NEA. Others include "Adequate protection of public health and safety," "Risk as low as reasonably practicable" [ALARP], "Safety as high as reasonably achievable" [SAHARA], and "Limit risk by use of best technologies at acceptable economic costs." Nuclear Energy Agency, "Nuclear Regulatory Decision Making," 2005, http://www.oecd-nea.org/nsd/reports/2005/nea5356-decision.pdf, at 17.

[128] Nuclear Regulatory Decision Making at 18.

[129] Nuclear Energy Agency, "The Characteristics of an Effective Nuclear Regulator," 2014, http://www.oecd-nea.org/nsd/pubs/2014/7185-regulator.pdf, at 17-18.

[130] The Characteristics of an Effective Nuclear Regulator at 25-28.

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