

Review of responses to discussion document “HSE review of the pre-licensing process for potential new build of nuclear power stations”

Summary

This report provides a high-level survey of responses received by HSE/NII on a discussion document posted on the Internet. Views had been sought on possible changes to HSE/NII's strategy for considering new nuclear plant that would include a pre-licensing phase looking at candidate design(s) for application within the UK.

The report illustrates how the responses were reviewed and how they have informed HSE's input to the DTI energy review. HSE's input take the form of an expert report (*The Health and Safety risks and regulatory strategy related to energy development: An expert report by the Health and Safety Executive contributing to the Government's Energy Review*) and an annex gives our proposals for a pre licensing process (*Annex 2 - The potential role of nuclear pre-licensing assessments for candidate designs*).

In response to a request for further information than this summary report will provide, HSE/NII are also intending to publish the comments in an appendix to this report, subject to gaining sanction from individual respondents.

Significant areas identified in the responses that have now been addressed in annex 2 of the HSE expert report include:

- The purpose of engaging with stakeholders was for the early gathering of views on possible proposed pre licensing processes. There will be further opportunities for external views on the process to be taken forward.
- HSE/NII has clarified the context of pre licensing by explaining how this would relate to other processes, such as the Site Licensing process that follows, and other consent process to be carried out by other regulators or government bodies.
- HSE/NII has ensured that annex 2 of the HSE expert report explains the opportunities for public input into HSE's consideration of the safety cases during the “pre licensing” process
- Pre licensing of a design would be against a generic “site envelope”. HSE/NII has now included within annex 2 of the HSE expert report that we would consider early submissions that particular sites fall within the proposed generic site envelope.
- Annex 2 of the HSE expert report has been reviewed to see what clarity HSE/NII can currently give on the form of the “Design Acceptance Certificate”, any included caveats, and its “bankability”.
- HSE/NII has ensured that our reasons for suggesting a 10-year period of validity for the “Design Acceptance Certificate” are explained.
- Annex 2 of the HSE expert report includes a commitment to produce further guidance on the process, and HSE/NII's assessment processes and standards.
- Annex 2 of the HSE expert report includes discussion on the effects on HSE resources. Additional resources will be sought so that pre licensing does not affect the effectiveness of HSE/NII as a regulator on existing facilities. The

annex also includes some discussion on HSE recruitment, increased use of third party resources, and possible use of overseas regulatory resource.

It should be understood that HSE has not yet been requested by any applicant to commence pre-licensing reviews. Publication of the HSE expert report (including annex 2 on options for pre-licensing) will allow for further engagement with stakeholders. It is proposed that the first stage in any process would include the development and publication of further guidance on the proposed processes, and stakeholder views will be sought on this guidance.

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1 INTRODUCTION

1.1 Background

As part of the Energy Review HSE/NII had a request from the Department of Trade and Industry (DTI) for advice on the potential role of pre-licensing assessments of candidate designs of new nuclear plant for the UK. HSE/NII has not had an application for a new power station licence for some time, so has taken the opportunity to review its licensing and pre-licensing strategy as it prepared this advice. The HSE response to the DTI Energy Review includes an annex which gives a proposal for a pre-licensing process.

As part of the review process, and to help ensure that we covered all relevant issues and views, HSE/NII sought comments from stakeholders (both from inside and outside the nuclear industry). The stakeholder engagement process included:

- a stakeholder workshop which was held on 3 March 2006, and
- posting a discussion document "*HSE review of the pre-licensing process for potential new build of nuclear power stations*" for comment on the HSE Internet site.
- a separate meeting of NGOs was held on 11 April, which brought together representatives from HSE, Greenpeace, Nuclear Free Local Authorities and the Welsh Anti-Nuclear Alliance, in which issues of concern were discussed and HSE was able to provide clarification on its licensing strategy and the potential role of pre-licensing assessments.

The discussion document itself came out of the stakeholder workshop. A large number of people or organisations were invited and more than thirty external participants attended. At the workshop HSE presented information on the licensing process and options for developing it further, but in a neutral way in order to encourage discussions. In fact, only about half of the agenda time was given to HSE presentations, with a considerable time given to Question and Answer sessions and free-ranging discussions. The discussion document was also framed to allow considerable flexibility in responses so that a wide range of opinions could be garnered from respondents.

The workshop and discussion document recognised that the current UK nuclear site licensing regime has been in place for some considerable time, and that during this time there have been considerable changes in the societal and industry backgrounds in which new licensing decisions would be made. As a guiding principle for the review, HSE considered that throughout any pre-licensing phase, as for the licensing process itself, HSE would need to ensure that high standards of nuclear safety and public confidence in regulatory decisions were maintained through transparent, rigorous, robust and effective regulation.

Readers of the discussion document were invited to respond on the potential role of pre-licensing assessments within any future UK nuclear licensing process. A number of areas where HSE would particularly welcome views were presented and each was followed by a series of questions considered relevant to these areas. Nevertheless, respondents were free to treat this list of areas and questions as non-exhaustive. HSE sought views on these and any other issues that respondents thought relevant to pre-licensing assessments and the HSE strategy for assessing new nuclear power station designs. HSE were constrained to submit its expert report to the DTI by the

end of June 2006, and therefore requested views and comments up until 28 April 2006.

1.2 Purpose of this report

HSE/NII undertook to consider all comments received in preparing our expert report to DTI. This document provides a high-level survey of the comments received, and acts to illustrate the range of responses and their significance to HSE's developing strategy for pre-licensing assessment.

The responses were analysed in some detail, and used to develop our response within HSE's expert report to the DTI's Energy Review team. An audit trail was set up so that we could confirm how each comment was sentenced. On looking at the nature of the comments it was not considered useful to report the process within a detailed blow-by-blow comment/response format.

It should be understood that HSE has not yet been requested by any applicant to commence pre-licensing reviews. Publication of the HSE response to DTI (including annex 2 on options for pre-licensing) will allow for further engagement with stakeholders. Additionally it is proposed that the first stage in any process would include the development and publication of further guidance on the proposed processes, and stakeholder views will be sought on this guidance.

1.3 Format of this report

This report is indented to allow an oversight of concerns and to confirm that these were taken account of in drawing up the proposed process.

The issues raised by the respondents were collated by themes, largely based upon the areas identified in the discussion document. Within these themes, more detailed sub-themes provided a convenient means of collating the issues. It should be appreciated that there is not be a one-to-one correspondence between the prompting questions in the discussion document and the sub-themes against which the responses have been collated.

The report is structured to give an overview of the responses, followed by detailed survey of the range of responses on the themes/sub-themes identified, and a commentary on the impact of the comments annex 2 of the HSE expert report.

In preparing the summary of the responses, we have chosen to use selected quotes to give some of elements of the comments. On occasion these are paraphrases intended to better illustrate the issues rather than restricting ourselves to verbatim quotes. We have used ellipses (...) and square brackets in a conventional sense to show editing amendments.

2 OVERVIEW OF RESPONSES

2.1 Nature and breadth of respondents

In all there were 35 respondents to the Discussion Document. Many of these were from the industry, with potential vendors, electrical generation companies (potential and current licensees), and companies offering consulting services all providing responses. Several responses were from NGOs including from organisations traditionally opposed to nuclear power. Some responses were from private individuals or academics either with interests in or concerns about present or future

nuclear facilities. There were also some responses from other regulators or government agencies, and from a union representing professional staff in the nuclear and power generating companies.

Some responses were very short – only a few lines in an email - whereas others were more fulsome. The majority of respondents gave responses to each of the areas or questions identified in the discussion document. Some provided additional supporting documents to their main responses.

HSE/NII has not attempted in any way to grade the responses, all included thoughtful contributions or challenges. In surveying the responses, HSE/NII were neutral as to the origin of each issue raised, and simply identified the issue so that we could capture the breadth of opinion.

2.2 Responses outside the HSE’s remit

The discussion document described the purpose of the current engagement:

This is not consultation about whether to build new nuclear power stations, or the pros and cons of doing so, or the safety of any new stations. Rather, it is about HSE’s approach to regulating the design of new nuclear power stations if we were asked to do so, even without a decision to go ahead with new build.

It should be noted that this review is limited to the general process for regulating a new nuclear power station design, and will not consider the licensability of specific reactor designs as we have not been asked to undertake any assessments of them.

Despite this many responses, both from industry, from NGOs and individuals included elements that went well outside our remit. In particular there were comments on issues such as the Justification and Public Inquiry and Planning Inquiry aspects associated with new nuclear build. Some of these are summarised in this survey of responses, since it is important that HSE/NII explain how we see our processes relating to other process. HSE however is not responsible for these other processes, so it was decided to share these detailed responses with the other government departments who do have these within their remit. This however was subject to any caveat attached requesting confidentiality. This was true of only one response.

2.3 Responses relevant to HSE/NII but outside the remit of this engagement

A number of respondents raised issues that were not related to the process of pre-licensing, but were instead related to the standards to be adopted in assessing candidate designs within the UK.

HSE/NII has recently been reviewing and updating its Safety Assessment Principles (SAPs). The reasons for this were essentially threefold: to build on learning from their application; to take account of changes in the industry, which in recent years has increasingly been involved in decommissioning and clean up; and to reflect the increasing emphasis on international harmonization including the latest development of the IAEA Safety Standards as best international practice. Various interactions with stakeholders were undertaken during 2005 and 2006, including seeking comments through the HSE Website both on various early drafts of particular sections and the draft revised document. Although that stakeholder engagement process is closed, where responses to the discussion document have been thought relevant to our

assessment standards, they were highlighted to the SAPs project team for further consideration.

Relevant comments included: the effects of climate change, the means of addressing uncertainties in off-site dose measurements, the application of the precautionary principle, etc.

3 RESPONSES GIVING FEEDBACK ON THE PROCESS TO GARNER VIEWS FROM STAKEHOLDERS

3.1 Summary of responses

Welcomed opportunity to contribute

Several respondents welcomed that HSE/NII were asking for views as part of our process of reviewing the role of pre-licensing. Some quotes:

"we welcome the opportunity for this specialist input into the wider DTI Energy Review...which is extremely valuable",

"we found the workshop on 3 March 2006 to be a very useful contribution to discussion of pre-licensing".

There was however some suspicion as to the motive of the review, as summarised elsewhere.

Concerns over timescales

Many of the respondents, especially from NGOs thought that the timescales over which responses to the discussion date was too short. Example extracts:

"... I would like it to be noted that one month for comment on this issue – particularly given the Energy Review and CORWM processes (and the Easter break) means that this is a severely curtailed process, taking place at a time when there are many demands on NGO resources. If any changes are made to the licensing process, the HSE must undertake a further round of consultation under appropriate Government guidelines, regardless of whether this might entail any regulatory changes or legislative requirements."

"I did not know about this consultation until alerted to it by a friend. ... there has to be a better more focussed way for alerting people to ...[web-based] consultations."

3.2 NII commentary on responses

Within our submission to the Energy Review HSE/NII has clarified that the process to garner views from stakeholders was not formal consultation on a change in a regulation; rather it was about the early gathering of views as part of drafting a proposal for a regulator's process. It is anticipated that there will be later opportunities for widespread comment on the proposed process.

4 THEME 1: PRE-LICENSING PROCESS

4.1 Detailed questions relevant to this theme

Q1 How might the licensing process be enhanced to reduce the regulatory risks to projects while improving regulatory effectiveness?

Q2 What role might pre-licensing assessments play in this?

Q3 *What would be the pros and cons of separating HSE assessment of plant design safety from assessment of site-specific aspects and assessment of the organisation of the licence applicant?*

Q4 *How could the interfaces between such separate assessments be managed to maintain or improve overall regulatory effectiveness?*

Q5 *Would additional guidance help to elucidate the relationship between an agreed programme of identified safety submissions and the gradual reduction of project risk as outstanding regulatory concerns are resolved?*

Q6 *Could HSE issue a formal regulatory report summarising its findings following separate assessment of a detailed design safety case and if so, how should the period of validity of its conclusions be determined and what caveats might apply?*

Q7 *How might the separate regulatory processes for health, safety, environment and security be better aligned?*

Q8 *What additional guidance on the licensing process would assist potential new entrants into the UK nuclear industry?*

4.2 Summary of responses

Regulatory Effectiveness

There is a common theme of needing to maintain and improve regulatory effectiveness, neatly summarised in the following comment

The detailed approval processes, particularly in relation to plant design and planning issues, should ensure that the design and operation of the proposed power station is subject to robust scrutiny, with public accountability.

It was also commented that

Regulatory knowledge and insights gained during a separate plant design assessment would also improve regulatory efficiency at the site specific and environmental assessment stages.

Pre-licensing - Principles

There was a wide range of views on the topic of pre-licensing, with a small number fundamentally opposed fundamentally to the concept. The majority of respondents felt that it could be a practical way forward provided that certain key principles were followed. These can be summarised as:

- Public engagement in the process
- Transparency of the process
- Measured use of overseas regulatory approvals
- Commitment to the existing UK regulatory principles
- Clarity on the outcome of a pre-licensing review.

Some examples of comments received are given below.

If the output of such pre-licensing assessment is to be useful in moving the process forward it is essential that it has a clearly defined status. For instance generic design issues dealt with by such an assessment should be accepted as resolved at any subsequent local inquiry.

Decisions made during pre-licensing must be ‘bankable’

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The public now rightly expects to be part of the investigation/examination and decision making process especially for 'innovative' and risky projects

The nuclear industry must be answerable to a transparent, thorough and robust mechanism of accountability. This should continue to include wide-ranging analysis of the local requirement for the plant with the availability for cross-examination, in the public arena, of industry experts - this should include health issues, safety issues and security issues

Measures taken to streamline the regulatory process should be balanced by devising a robust, transparent and accountable set of procedures capable of addressing public concerns.

We believe the current process is already inadequate in terms of participation and accountability and the use of pre-licensing can only make matters worse.

The following suggestion was made by one respondent

It would be valuable if, in addition to NII's review of the new plant licensing arrangements (including the assessment of plant designs), the possibility of separate pre-licensing assessments of potential sites could be considered.

Pre-licensing - Framework

The common themes that run through the suggestions on framework are clarity, coordination and accountability.

On the licensing process side ... suggest a high level gated multi-stage approach is developed, which treats each licence application as a project; the first stage would agree the concept of an acceptable design, the second stage would address specific details related to a specific reactor model, and the third stage would consider site specific issues (as well as the capability of the applicant/eventual license holder to operate the plant safely and the safety management arrangements that the applicant is proposing). In developing such a process clarity of what is required to satisfy each stage is vital and moving from one stage to the next is consequent on meeting these requirements, with clear focus on the "front end" needs. Approval at each stage would be regarded as final unless in an extremely rare circumstance material challenging actual principles came to light from other external regulatory sources (i.e. another international regulator). Reaching final agreement to stage three of the licensing process would be the trigger for construction to commence.

...there also needs to be a licensing and planning process that:

- provides for public participation in the consideration of the generic issues of new nuclear construction such that these issues do not have to be re-examined as part of the planning process for each potential site;*
- enables the site specific issues to be the focus of the planning process for each potential site;*
- results in the granting of the necessary licences, authorisations and consents within predictable and streamlined timescales, in a manner that progressively reduces regulatory and project-related risk;*
- encourages competition by pre-licensing standard international designs, thereby requiring the minimum of modification for the UK market and allowing final selection of a site-specific design to be as close in timing terms as possible to the grant of a licence;*
- enables all the necessary licences, authorisations and consents to be in place before the decision to start construction; and*

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- *provides strong co-ordination and management of the various Government and regulatory elements so that agreed targets are met within planned timescales.*

On the resources issue, the regulator needs to identify and acquire the qualified resources up front to undertake the licensing processes to a timescale agreed with the necessary authorities and with the applicant.

Pre-licensing will lead to a “Licensability Statement” that has a number of conditions attached. This will be issued before the start of a public inquiry, which is normally part of the section 36 consent process.

Pre-licensing Assessments

There were a number of comments on detailed aspects of undertaking the assessment of designs against UK regulatory requirements. These tended to be focussed on development of benefit from previous approvals from other regulatory bodies and the use of international standards as a benchmark. Some typical comments are given below.

However, the main UK and European utilities have prepared a set of common utility requirements, including safety, for new reactors to be built in Europe, which is known as the European Utilities Requirements Document (EUR). The NII should be encouraged to review the safety related requirements in this document for alignment with its Safety Assessment Principles (SAPs) and confirm its usefulness as a basis for a pre-licensing assessment.

Greater use of assessments by regulatory bodies in other countries would have several benefits:

- *Access to a greater body of knowledge and experience than current NII human and financial resources can provide*
- *Less chance of risks being missed, and better suggestions for dealing with them because of the greater number of bodies involved*
- *Better ongoing regulatory effectiveness through sharing of data and experience*

Some suggested improvements to the assessment process

- *Allow applicants and vendors to examine candidate designs against a “generic” UK site so that the majority of issues need only to be considered once for a particular design*
- *Enable more credit to be taken from international design safety assessments carried out both by vendors and overseas regulators. For example HSE could review how overseas regulators had been satisfied (examining their processes and criteria) and identify where it was possible for them only to review detailed material by exception*
- *Review the way the ALARP principle is applied, in the UK, to take explicit account of the potential safety detriment associated with amending established international designs. This should be explicitly recognised when assessing whether additional or different features should be introduced into the design for the UK.*

Separating plant specific issues from site and licensee aspects

The responses from to this question raised a series of pros and cons, but on the whole, the consensus was that the separation was feasible, given an appropriate framework within which it would work. A sample of pros and cons are given below.

Pros

- *Enables focussed consideration of the design fundamentals*

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- *Promotes a standard design across a number of sites, and even operating organisations*
- *Enables the detailed design assessment to be done only once*
- *Design assessment can start earlier i.e. before operator or a site is determined*
- *Generic and design issues need only be considered once for each candidate design – there is no need to revisit for each site licence application*
- *Site licence application assessment can focus on local site specific issues only*
- *It brings efficiency by securing a common approach for common issues across designs, sites and across organisations. All relevant parties can participate in pre-licensing assessment of designs without commitment to a site-specific proposal. This also gives flexibility for industry to develop site licensee structures in parallel with design review, without pre-judgment on the best model.*

Cons

- *Risk of actual site data falling outside the envelope for the reference site. However this is a risk for the licence applicant and not the Regulator(s) and can be mitigated by careful selection of parameters for the reference site.*
- *Same comment applies for the Operating Organisation delivering what was assumed in the pre-licensing phase.*
- *A standard design that is appropriate across a number of sites may be more costly (potential trade-off here between site applicability and numbers of units potentially to be constructed – primarily a project/ applicant consideration)*
- *Makes the application of principles such as ALARP in an overall holistic fashion more difficult*
- *Could cause an imbalance in requiring extra levels of safety in the design to compensate for less well developed (or understood) organisational arrangements by the proposed licensee in terms of safety in operation*
- *lack of a “driver” to push the review schedule in the absence of a “real” license application; and*
- *the need for “commercially acceptable” certainty that the extensive pre-licensing work will not be undermined in the next stages.*

Concerns have been expressed about the role of public scrutiny being reduced as a result of following this process, summarised in the comment below.

It seems to be assumed that if design were separated from the two other matters the design issue could be excluded from detailed scrutiny at a public inquiry. This seems to us to be naïve: during the period whilst the design issue is purely abstract and non-site specific, the community subsequently chosen for the actual site licence application may not have voiced its concerns. Conversely when the design becomes site specific, much political argument and legal ingenuity will be deployed locally to ensure that the design will be challenged again at the inquiry, like it or not

This would have the effect of reducing the overall timescale to build new nuclear power stations (except perhaps the first of a kind) by reducing the regulatory uncertainty. It could however possibly lengthen the time to license the first of a kind reactor unless pre-licensing was undertaken well in advance of particular applications.

The overall approvals process might also be streamlined further if a set of standard criteria, against which a proposed installation’s management and operational capabilities could be assessed (and approved) at this time, were agreed.

Generic site envelope

In developing a generic design of plant, assumptions must be made over certain key site driven parameters. Typically these relate to geotechnical matters and external hazards, but will also extend into the local geography and population profile for consideration of emergency arrangements. The development of such a site profile, and the subsequent pull through of the design into a site specific one without substantial alteration were seen as manageable processes. The following comments give an indication of the views.

Although UK licensing is licensee and site specific, pre-licensing and the flow through to formal licensing must be seen as parts of an overall process

They are three separate assessments (i.e. plant safety, licensee capability and site-specific) requiring different skills and the involvement of different teams and they should be undertaken as such. The Terms of Reference under which they are undertaken should make accountabilities clear. We need to ensure that there is an element of common membership of assessment groups to facilitate communication and the flow of information.

Striking an appropriate balance between generic versus specific site criteria i.e. specifying the bounds of the ‘generic site’ envelope is a ‘smart’ judgment for the vendor/site Licence Applicants, with a view to balancing the potential costs of ‘overspecification’ in the generic design, versus the benefits of minimising site-specific changes (which may be decided in consultation with potential site Licence Applicants Owner/Operators, utilities). Any subsequent changes, which take the site-specific design outside the Pre-Licensed ‘generic envelope’, would then need to be appropriately justified in the site-specific Licence Application.

Report and Period of Validity

There is a general consensus that a formal licensability report by HSE is essential, for example a typical comment was.

We believe that a formal regulatory report by HSE of its findings will be essential to enable due diligence of the project by potential project investors and other stakeholders, as well as to demonstrate transparency to all parties including Parliament and the general public.

The degree to which this report is “bankable”, a foil for future scrutiny of aspects of the safety case, the nature of any caveats, and the period of validity have each attracted a variety of responses, as summarised below.

Bankability

It is important that, at the end of a pre-licensing assessment, a “Letter of Comfort” or “Licensability Statement” is produced that provides a clear position on the acceptability of the design, all significant issues that still have to be resolved and any ongoing safety related work that has to be completed before a licence can be granted. In the interests of regulatory certainty, this statement needs to be strong enough so that formal reliance can be placed on it during the next stages of the process.

Caveating

If HSE could issue such a report, it would have to be so hedged about by caveats to ensure independence of action subsequently (in the light of the ratchet effect of the duty to ensure that risks were reduced so far as reasonably practicable and of the particular site application), that its value to a potential developer might be limited.

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Ideally there should be no caveats, but if any are necessary the means by which they will be resolved should be agreed and included in the report to provide the necessary assurance that all significant issues are bounded.

As in any other safety case the period of validity and any caveats should be proposed by the applicant and accepted or not by NII. The report should address the timescales and caveats.

Period of Validity

A variety of periods of validity have been suggested from 5-20 years (see below), with the potential for intermediate reviews. The longer validity period suggested is claimed to provide a degree of surety over large programmes of new build (8-10 Units). Some typical responses are given below.

As in any other safety case the period of validity and any caveats should be proposed by the applicant and accepted or not by NII

...suggested that a revalidation should be performed every 5-10 years to ensure consistency with best international practice

...a period of validity similar to that set for periodic safety review would seem to be reasonable. However in order to allow for the final licensing and construction periods the validity should be extended to at least 15 years

As to period of validity, we would suggest that the Sizewell B project lifecycle can provide a useful template, with license to construction given in 1987, license to operate in 1995 and the first ten-yearly periodic safety review currently being concluded with limited findings. Therefore we would suggest a period of validity of 20 years

The period of validity should be sufficient to launch a new NPP project, and build and operate the installation; in addition, it must make it possible to continue with the construction of other new NPPs designed and built to the same standard. Therefore the validity of the statement could be up to 20 years

Other regulators

Other regulators involved in the process of Pre-licensing would be EA/SEPA, OCNS, HPA, as well as interaction from OGDs, DEFRA and DTI, and advice from other government bodies such as NDA and NIREX. Clearly, there are a large number of stakeholders and complex interfaces that would require management. It has been suggested by a number of respondents that DTI should act in this coordination role, and by others that an industry led group would be better placed given the commercial imperative. There are, however, good working relationships between the various regulators already in place. There may also be a need for some legislative adjustments to allow these regulators to participate in a stepwise licensing process.

Guidance for Applicants

There was a general consensus that there would be a need for greater guidance to applicants on the depth and breadth of submissions for Pre-licensing. Typical comments were.

Guidance on the interfaces between the processes and requirements for health, safety, environment and security, including organisational interfaces (with other regulatory agencies) would be helpful. Moreover, a summary document outlining the major licensing related activities from the start of license application to the start of operation would also be valuable, particularly if new regulatory and licensing requirements are established. This document should include the major steps, information required at each step, milestones or control points, expected timeframe for each step, interfaces

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with other regulatory agencies and government departments and with the members of the public.

Safety submissions should be based on the content identified by the IAEA for safety reports and should be the subject of early discussion by the NII, EA/SEPA, OCNS, the group of potential licensees and plant designers. A stage in pre-licensing that is proposed ... is early identification for each design of any significant safety issues that would either prevent licensing in the UK or require major modification of the design. This is an area that would profit from clear guidance for NII assessors, so that issues are identified in a consistent way against common criteria. Similar guidance would be helpful to aid decisions at the end of the assessment process on issues that need to be identified in an assessment report and a design assessment “certificate” ...

... the emphasis from industry is on a predictable process that is designed to progressively reduce project risk. This must be recognised and should inform the culture within the regulatory body accordingly.

As part of the NII’s review of licensing procedures some revised guidance/new mechanisms should be considered in terms of stakeholder communication. There must be a clear set of commonly understood criteria relating to safety and all other aspects of licensing. It would be beneficial for the NII to consider reviewing alignment with standard European utility requirements.

At a later stage, when a potential licensee for the first site is identified, a set of standard criteria could be identified, against which a proposed installation’s management and operational capabilities could be assessed. This would make the preparation of a Safety Management Prospectus much simpler, particularly if the potential licensee were not a current UK nuclear licensee.

We suggest that DTI, as sponsor for the nuclear industry, should offer training courses describing the UK nuclear regulatory process aimed at potential new entrants into the UK nuclear industry.

... priority must be for HSE to engage with the entrants (vendors and utilities) to ensure mutual understanding and ...[a] consensus on a streamlined way forward for UK licensing around a regulatory strategy/project plan. Pre-judgements on the way forward should be avoided ... new entrants will have substantial and transferable experience from their home countries.

4.3 NII commentary on responses

Many of the comments cover processes outside the control of HSE/NII, such as Justification (responsibility of UK Government) and Public/Planning Inquiries. Within annex 2 of the HSE expert report HSE/NII has made it clear that the pre-licensing process is just one of a number of processes that must be completed prior to the granting of a Site License. This has also been explained diagrammatically.

Annex 2 of the HSE expert report includes a commitment to increased public input to HSE/NIIs considerations of the safety case for candidate designs for pre-licensing and licensing. It is hoped that the increased opportunities for public input to our processes can be seen as providing advantages in terms of accountability and transparency, and that HSE has not approached this review with ulterior motives.

The proposed pre-licensing process does not at present include the possibility of paralleling some aspects of the licensing phase with the pre-licensing work. In particular it may be possible to examine at an early stage whether a particular site is within the generic envelope against which Design Acceptance is being sought. This may slightly shorten this phase of the process. It is thought that this is not a significant extension to the proposed process and could be considered. It should be

understood that Phase Two (Licensing) is viewed as being quite short following Design Acceptance, and that other aspects are more likely to affect the overall timescales.

There are issues on how enveloping a generic site envelope would be, but this is a matter for more detailed discussion if and when HSE/NII are asked to commence any Design Acceptance work.

Within the annex HSE/NII has clarified our views on the form of the Design Acceptance Certificate and its "bankability". HSE/NII feel that there are limits on how closely the caveats can be determined in advance.

HSE/NII has justified our reasons for suggesting a 10-year period of validity, and recognise that industry would prefer a longer period, consistent with validity periods in other countries. HSE/NII believe that, in any case, UK legislative requirements would expect applicants (vendors/licensees) to be proactive in changing a design if international experience suggests the need or if relevant good practice changes during the period of validity.

The annex is deliberately neutral as to whether applications for pre-licensing may come from vendors directly, from licensees directly or from some grouping (maybe coordinated via DTI or some group of the "good and the great"). We believe that this is not for us to determine. In any case, that there are resource and priority issues no matter how many pre-licensing assessment are requested.

The annex includes a commitment to producing further guidance as part of the initial activities. The precise form of the guidance is not indicated, but it may include workshops / training courses once a process is fully developed.

5 THEME 2: REGULATORY PRIORITIES AND RESOURCE ISSUES

5.1 Detailed questions relevant to this theme

Q9 How should competing licence applications or requests for pre-licensing assessments of candidate designs be prioritised?

Q10 Who should prioritise these – the regulators, Government, a body representing the nuclear industry, etc?

Q11 HSE may find itself in the position where it has already started (and at least partially recovered costs for) a pre-licensing assessment of a particular design at the behest of one company, when a different company makes a similar request. How should HSE deal with this situation without unfairly benefiting the second applicant over the first?

Q12 One way of dealing with possible multiple requests might be to set an initial period for the submission of expressions of interest and to programme regulatory resources on the basis of applications received during that period, prioritising any subsequent applications separately. Would such an arrangement be workable?

Q13 How should HSE be financed to cover the resourcing requirements associated with any pre-licensing assessment of new reactor designs?

5.2 Summary of responses

Number of competing designs

Several comments discussed the number of competing designs that may require pre-licensing assessment. Most thought that there were quite a small number of

competing designs ("*May only be one "runner"*"), or "*Possibly only two designs in contention*", but others, particularly from the industry thought "*Currently at least three*".

Prioritisation

A) Versus existing work

There was a common consensus that existing regulatory effort should not be deflected from existing plant onto New Build without very careful consideration.

Some respondents were of the view that "*... regulator needs sufficient resources for all and any demands.*"

B) within pre-licensing process

There were a wide variety of suggestions for prioritisation within the pre-licensing arena. These broadly fell into the following categories.

- No prioritisation, all designs which meet certain basic safety criteria should be considered
- An industry led body should coordinate and prioritise itself the most likely candidates and propose this to the regulator
- A DTI led body should coordinate with industry and regulator(s) to act as the prioritisation body. It was further suggested by some that an open invitation should be issued and following submissions to that, prioritisation undertaken.
- A first come first served approach, following satisfaction that certain basic safety criteria had been met
- Submissions should be made, and then a moratorium on new designs being proposed until a period of time had elapsed.

There are potential additional complications on phasing of new entrants and existing designs which were also raised.

Prioritisation could be based on a number of criteria, including "*degree of proven technology*", "*credibility of proposers*", "*waste arisings*", or a more complex arrangement, however one respondent expressed concern over an overly academic approach to this.

Funding/Cost allocation

There was a general consensus that the bulk of the costs of pre-licensing should be borne by the licensee/ vendor. There were various suggestions over the timing of this payment; the range of options is given below.

- Pay as you go type arrangement
- Fixed price type arrangement
- Initial funding from the public purse, recovery at a later stage, as some form of royalty.

There was concern expressed by some that the financial liability to the applicant needed to be defined with some certainty to allow appropriate project budgeting. It was also noted that there might be some indirect costs associated with public stakeholder engagement. A further comment made by a number of respondents was

that “*Funding by the applicant (Licensee/consortium) (helped) to ensure commitment and balance sheet strength.*”

It should be noted that there are other regulators whose costs will also need to be accounted for in some way as part of any pre-licensing activity.

Resourcing

The degree of resource required, clearly arises partially out of any decision made on prioritisation. The general messages from the respondents are summarised below.

- There should be adequate resources for whatever is asked of the regulator.
- The NII needs to be mindful of increasing workload due to accelerated decommissioning proposed by NDA
- A new branch within the regulator should be devoted to this topic
- Greater use of broader HSE resources
- Supplementary resources through technical design chain

5.3 NII Commentary on responses

We have included in annex 2 of the HSE expert report an explanation that HSE/NII is charged to maintain an effective role as a regulator, and is aware that there are other claims on its current resources from extant work on existing facilities. Additional resource would be sought to respond to any requests for pre-licensing. The amount of resources could be significant if industry required more than one design to be considered simultaneously

Providing sufficient resources for any pre-licensing process is essential. The HSE/NII staff will need to be SQEP (Suitably Qualified and Experienced Personnel). Great care will be needed in selection of staff, recruitment/ training of staff, and where necessary engagement of third parties for specialist input.

Prioritising designs for pre-licensing gives challenges. The pre-licensing process proposed is a step-wise process where the submission is looked at in increasing depth and detail, and resource requirements are greater for the later “Detailed Assessment of Design Acceptability” stage. The earlier steps may have the benefit of “weeding out” some candidate designs, if these are felt to be fundamentally incapable of being licensed in the UK without substantial modification. This could be of benefit in reducing resource demands on HSE/NII.

Annex 2 of the HSE expert report identifies that the practicalities of recruitment and development of the new recruits into effective nuclear regulators would limit the speed with which HSE could progress simultaneous assessments. It suggests that applicants should coordinate their approaches to and that others (e.g. DTI) may need to coordinate a suitable set of designs to be put forward for assessment.

6 THEME 3: OVERSEAS DESIGNS

6.1 Detailed questions relevant to this theme

Q14 How should applicants ensure that their safety submissions demonstrate compliance with UK health and safety requirements, in particular the duty to reduce risks so far as is reasonably practicable?

Review of responses to discussion document: "HSE review of the pre licensing process for potential new build of nuclear power stations"

Q15 In discussions involving reactor vendors, design authorities and plant suppliers, how should applicants ensure that the predominant role of the nuclear site licensee in managing nuclear safety is preserved?

Q16 To what extent should HSE give credit to safety assessments performed by overseas nuclear regulators while fulfilling its duty to secure high standards of nuclear safety for the UK public and workers?

Q17 How might HSE assess other regulators' work without impinging on their duties and roles, and give such credit?

Q18 How might applicants utilise overseas regulator's safety assessments and take credit for them in their safety submissions to HSE?

Q19 How might HSE develop an understanding of the context within which the overseas regulators made their decisions, sufficient to enable it to judge the weight to be given to those decisions in a UK context?

Q20 How should applicants ensure that HSE is provided with the access to staff and facilities of overseas regulators, reactor vendors and plant manufacturers necessary for it to judge the quality of their analyses, assessments and products, and validate the parts of the applicant's safety submissions that rely upon them?

Q21 The flexibility inherent in HSE's goal-setting approach may allow for variations in design and operation from those accepted in the country of origin. How far should HSE go in ensuring that design and operational standards accepted during the UK licensing process remain consistent with regulatory requirements in the country of origin?

Assessment Standards

It was generally agreed that there was some benefit to be gained from the use of international standards for nuclear safety, the degree of reliance on them however varied across respondents. Typical responses included

1. Comply with all relevant UK legislative regulations and demonstrate International best practice.
2. UK already moving towards international standards, e.g. use TechSpecs, BS now covered by equivalent EN standards.
3. NII should closely review the safety-related requirements of the European Utilities Requirement Document (EUR) as a basis for pre-licensing.

Credit for Overseas Regulator Approvals

There were a wide variety of responses on this issue, ranging from giving full credit for other regulator approvals to discounting them almost completely. The key proponents for taking greater credit focussed on the international dimension to Generation III reactor designs, and to the development of international/ European standards. Those opposed to greater credit focussed on the goal setting approach used in the UK, the need for formal demonstration of ALARP, and the potential reduction in public confidence of making substantial use of other countries assessments. It was also suggested by some respondents that interaction with other government bodies and NGO's might give a broader view over applicants' suitability. The issue of accessibility to public scrutiny of overseas regulatory judgements was also raised as a potential issue. An illustrative range of comments is given below.

- *Full credit for overseas licensing.*
- *Given the international nature of both the nuclear industry and the mature development of organisations which transcend national boundaries (i.e. INRA.,*

Review of responses to discussion document: "HSE review of the pre licensing process for potential new build of nuclear power stations"

WENRA, IAEA, INPO, WANO, etc) credit should be given to safety assessments approved by national regulators from other countries and should be used as evidence in reaching approval

- *...work done through INRA and WENRA [could] be turned around so that ... contributing safety assessments can be recognised as suitable building blocks within the UK regulatory framework. ... consideration of compliance with international standards and ... IAEA design principles. ...[to] enable the safety benefits of standard designs and common operational practices ... to be realised, as a[n] alternative to the bespoke UK-tailored approach ...*
- *Full risk assessment to UK standards.*

Some respondents commented that it would be beneficial/ necessary to make use of support work undertaken by other regulators as part of their review of designs for pre-licensing for example.

To some extent, credit could be given for work done by the applicant and in assessments performed by credible overseas regulators in areas such as:

- *R&D (specially legacy R&D and R&D database),*
- *computer code development and validation (for codes that have proven capabilities for considerable amount of time in other jurisdictions), and*
- *codes and standards that would meet the intent of UK requirements (e.g., ISO, IAEA, CSA, ASME), and*
- *decisions on regulatory treatment of inherent design features*

The IAEA Convention on Nuclear Safety peer reports should ... be helpful in confirming areas of others' competence (and areas for improvement).

Inter Regulator Working

There was a clear consensus that an exchange of information between regulators would be beneficial. The degree to which this should be formalised however varied. Some respondents considered that

There may need to Government to Government co-operation to facilitate this.

Bilateral agreements between the NII and other nuclear regulators...extended to cover harmonisation of safety standards...

Group of regulators to agree on common basis for assessment and approval – very purpose of Multinational Design Approval Process (MDAP) which is being proposed by the USNRC.

It was also noted by a number of respondents that there may be a need for some financial exchange or other quid-pro-quo if extended works with other regulators was needed.

Some respondents suggested that it would be beneficial to have a pre-licensing process that was non-country specific; rather one that was organised by a group of regulators, under the guidance of internationally agreed guidelines.

The EPR currently underway in Finland was suggested as an example of where French and German Regulators worked in collaboration with those in Finland. The Finnish regulatory authorities had previously reviewed a suite of designs, and agreed those changes necessary to meet with their regulatory expectations.

Role of Licensee

At the pre-licensing stage, there may not be a licensee identified, however beyond this stage the applicant for a nuclear site licence would need to be specific in its identification of a specific site and be subject to the other two aspects of assessment. There were a number of comments that discussed the role of the licensee, which are summarised below.

By time of licensing the licensee will need sufficient training, etc., to be intelligent customer / intelligent buyer, and sufficient SQEP staff to operate the plant.

A licensee only needs to be defined at a later stage (licensing rather than pre-licensing). Nevertheless, prospective licensees will prefer to be involved in pre-licensing, otherwise decisions are made by the vendor and regulator.

The site licensee must be familiar with the issues related to both phases of licensing.

If vendor led - concept of "Reference Operating Organisation" which can capture needs in pre-licensing assessment.

Modifications to Overseas Designs

It was a general consensus that modifications to established designs should only be undertaken following a robust demonstration of a net improvement in safety, and a demonstrable need in order to meet UK expectations. There were a variety of views around this central tenet however, example of which are given below.

Changes should be minimised to allow comparability of plants during operation: as with the aircraft industry, maximum safety is achieved when all operators of similar machines make reports to a central body which collates and analyses safety aspects, and makes recommendations

...consideration should be given as to how the benefits of not making changes to a design can be given appropriate credit by the regulator. There are large safety and operational benefits in terms of operating staff transferability/familiarity, spares, etc. and there is often a safety disbenefit associated with changes

If differences are driven by national requirements, there is a clear basis for justification, without it having to impact on the Country of Origin. The Licensing of EPR in Finland shows exactly how this can work in practice

6.2 NII Commentary on responses

The fundamental obligation on HSE/ NII is to ensure that proposed designs are compliant with UK legislation.

Using the above as a starting point, the value that can be ascribed to overseas regulators' approvals becomes clearer, and this is summarised in annex 2 of the HSE expert report. The findings of such overseas regulators approvals would allow better targeting HSE/NII resources. The extent to which the assessments would be taken into account would depend on the depth of information provided by the applicant on the regulatory issues identified by overseas regulators and on the evidence it submitted on their resolution. HSE/NII would then test the robustness of the claims made for resolution of overseas regulatory issues by direct discussions and correspondence with the relevant regulators, and would give this information weight according to the quality of the interactions achieved. This is because it is our the duty as UK regulator to conduct an appropriate safety assessment of proposals for new nuclear build in accordance with the national regulatory requirements of the UK,

including the legal requirement to demonstrate that the risks have been reduced to a level as low as reasonably practicable (ALARP).

Annex 2 of the HSE expert report recognises that the pre-licensing stage could be vendor led, but describes the importance of transfer of knowledge from vendor to potential licensee as a key issue for resolution prior to the granting of a Site Licence.

The comments from some of the respondents include some concerns on the effects of modifying existing, well-developed designs; however the position is very clear. Modifications to meet UK requirements would only be required if they were judged as reasonably practicable, and in the first place it would be the applicant that should look for these changes, prior to submitting a design to HSE/NII. Design Acceptance should be viewed holistically; a modified design should not be viewed as a developed design with a bolt-on extra. Issues of fleet consistency, whilst of a commercial benefit are not necessarily of equal safety benefit. This has not been taken forward in the annex, the text is clear that the purpose of both pre-licensing and licensing processes is to judge a design’s ability to meet UK requirements.

7 THEME 4: LESSONS LEARNT FROM PREVIOUS LICENSING EXPERIENCE OF NUCLEAR POWER PLANT

7.1 Detailed questions relevant to this theme

Q22 What lessons can be learned from the Sizewell B licensing and subsequent Hinkley Point C inquiry experiences?

Q23 How might the industry or others help improve the effectiveness and efficiency of the licensing process?

Q24 Might there be scope to have greater clarity of the respective roles and scope of regulatory processes and local planning processes and inquiries, and how they are linked together?

Q25 Is the licensing process sufficiently transparent?

Q26 How might public confidence in the outcomes of regulatory assessments of candidate designs and licensing applications be enhanced without diluting duties?

Experience

There are varied comments over the effectiveness and approach adopted in the Sizewell B Public enquiry, however it was generally felt that a better approach could be developed.

One set of perspectives considered that the inquiry allowed public scrutiny of the safety case, which resulted in some design changes to reduce public risk. A contrary view was that significant time and uncertainty were introduced into the process and that resulted in limited changes to the design.

Some respondents commented that the inquiries did not give sufficient time to what were genuinely “local” concerns, as opposed to more general safety and policy type issues.

A number of respondents wanted much clearer terms of reference for a future inquiry, and a much closer definition of the framework within which it sat, and its relations to other consents and pre-licensing itself.

Coverage of Inquires

There was a wide range of views on this subject. Typical examples were.

"The Public Inquiry should not consider plant safety. That should be an issue solely for the Regulators."

"The inquiries took too long and encompassed too many different issues. Issues of finance, national energy needs, safety and local environment are separate and should be dealt with as such."

"Debates about what level of safety is "adequate", or whether there should be new nuclear build at all, should not be held at the inquiry but should be resolved beforehand."

"The system for assessing licenses for nuclear power stations does need to change and to modernise and, in that respect, to enable and to facilitate public participation and stakeholder engagement at all stages."

There was a fairly common view however that coordination of the requirements of all regulatory bodies (EA & SEPA, HPA and OCNS) would be beneficial.

Equally, there was a reasonable consensus that before entering an inquiry, the NII should have formed its views on the particular design under consideration, and that the design should not still be fundamentally evolving.

Regulatory input to Inquires

There was a consensus that there should be a clear regulatory view at the inquiry stage, and that hopefully, all significant issues have been resolved before this stage is reached. A typical response was

"This means that the Regulators must be in a position to state publicly at the PI that they have no objections to the proposals, that they expect to be able to licence it, and that it will not be licensed until they are fully convinced of the plant's safety. The Owner Operator must also present a robust case and be prepared to rebut objections when necessary."

Role of public

There was a clear consensus that engagement of the public in the licensing process is a fundamental requirement.

"The current legislative commitments to Freedom of Information concerning environmental information requires such transparency"

Public participation is a requirement stemming from Convention on Biological Diversity and its concomitant Agenda 21; from the Aarhus declaration and from the EC Directive on Freedom of Information (EEC, 2990) which has been transposed into UK law.

The system for assessing licenses for nuclear power stations does need to change and to modernise and, in that respect, to enable and to facilitate public participation and stakeholder engagement at all stages."

Public participation is a requirement of the UK Sustainable Development strategy.

Some respondents noted that there might well be restrictions on data that could be released to the public on security grounds or commercial sensitivity. However this was tempered by the view that "...If during the process the current provisions and exemptions to curtail release of information within FOI legislation are employed, then there will be no confidence in the process."

The public's role and the timing of their contributions are further discussed under Theme 1.

Improve efficiency of licensing process

There were several common themes that came through from the respondents. The responses below are extracts.

Management

all involved ... should agree and comply with a programme of submissions and regularly monitor against the agreed programme flexing the resources appropriately to ensure programme slippage is avoided

Regulatory permissioning should be 'joined-up' so that there are no restricting interfaces between them e.g. Environment Agencies, NII, OCNS

Resourcing

The NII needs to plan for its own support needs and to be able to contract support from appropriate organisations/bodies. It needs to be able to access Technical Support Organisations

Standards

...by pursuing standard international designs that meet established safety and operational standards. The development of the URD and EUR ... are examples of this.

make wide use of recognized codes and standards such as the RCC-M or the ASME code for the main nuclear systems and components.

Process

Through workshop and optioneering processes rather than multifarious consultations or lengthy inquiries. The licensing process itself should be incentivised.

Industry are very supportive of ongoing consultation and the need for dialogue to agree for example regulatory strategy/plan, approach to standardisation in the context of holistic and proportionate application of ALARP and programme management arrangements.

Clarity vis a vis planning process and inquiries

There are several common themes from respondents

- Need for greater clarity of the individual processes
- Need for greater clarity on the integration of individual processes
- Clarity of the responsibility for separate and integrated processes
- The need for this information to be made available
- The need for clear lines of communication for all parties involved.

Typical comments were

The respective roles of HSE and the planning authorities should be made clear

It would be useful to have greater clarity of roles, scope and linkages of the various processes [to] ensure that there is no redundancy amongst the various parties' assessments and eliminate the discussion of issues that fall outside the mandated scope.

The clarity of the roles and responsibilities could be improved as part of an overall project management initiative led by, say, DTI. ...Clarification of the roles of the various forms of public consultation is necessary.

The HSE and other regulators can help by explaining more accurately they roles and how they will present a clear safety case for a generic design to the public before it is 'handed over' to a planning inquiry at a specific site

it will be beneficial to optimize the schedules of the different processes and the links between them in order to shorten the overall decision-making process

We would suggest an in-depth audit of information processes, perhaps involving outside consultants leading to the creation and implementation of an integrated stakeholder communications strategy.

Transparency of licensing process

There were a number of comments expressing the view that in a modern setting secrecy was not acceptable, and all respondents accepted the principle of the public having a role. Some typical comments were.

The involvement of the public is consistent with the views stated in "The Tolerability of Risk from Nuclear Power Stations" (1992) ("TOR") that "...final judgements about whether a given risk is tolerable are not matters for experts alone but for people who have to bear the risk and who are therefore entitled to be given the best possible technical advice about them."

Public scrutiny needs to be a major aspect of all the decision processes associated with new nuclear plant. It is essential that the pre-licensing process is transparent and offers the opportunity for public comment on safety issues

...careful thought needs to be given to ensuring how confidence can be maintained in ensuring a transparent and participative process in the face of potential claims to commercial confidentiality or secrecy for ostensible or real security reasons. If this is not done, any authentic commitment to an open transparent process will be undermined so that legitimacy will once more be lost.

Safety cases resulting from applications for the NII to accept new reactor designs must be published and a suitable period allowed for public comment before the HSE decides whether or not to accept them

7.2 NII Commentary on responses

HSE/NII acknowledge that in a modern licensing process, the role of the public, and associated transparency of decision making are essential in maintaining stakeholder confidence. This issue cuts across both the pre-licensing and licensing processes, and also any public inquiry that may be held.

Whilst the Sizewell and Hinkley Point Inquiries were beneficial in many ways, their effectiveness from a public examination of nuclear safety perspective could be improved. It is necessary however to have a clearer framework than currently exists within which public scrutiny can be exercised.

Extending the concept of a clearer framework into the (pre) licensing process will allow a clearer definition of the process to be followed and the roles and responsibilities of individual government bodies. In addition, the management required, resourcing needs, communications strategy and standards to be applied can also be better defined.

None of this greater clarity should in any way bring about a diminution of public confidence or in any way fetter the discretion of the regulator(s). Development of a framework clearly requires interdepartmental cooperation and coordination across government.

All these comments have been taken account on in the annex 2 of the HSE expert report covering pre-licensing.

8 THEME 5: REGULATORY STRATEGY

8.1 Detailed questions relevant to this theme

Q27 Can the current goal setting UK nuclear site licensing system continue to respond robustly to the demands of a changing, market-led nuclear industry?

Q28 Are any changes to HSE's regulatory approach to new nuclear reactor design necessary or desirable to provide continuing confidence in the current regulatory system?

Q29 Might some features of overseas regulatory systems offer benefits to the UK?

8.2 Summary of responses

Advantages of fleet of similar stations.

Goal setting

There is a general consensus that a goal setting regime can provide the necessary robustness to the licensing process since

"it demonstrably encourages innovation in arrangements for nuclear safety, safety and environmental protection, which do not necessarily happen under other regulatory regimes"

When applied correctly, it results in

"a sensible application of ALARP to plant designs that have sound deterministic safety cases supported by probabilistic assessments to show that the risks are properly balanced with cost and complexity."

Some respondents expressed concern over the greater potential for open-endedness in a goal-setting regime. This led to suggestions that it would be useful to develop more detailed guidance such that acceptance criteria could be made more *"measurable"*

This was also reflected in concerns over the ability to establish and meet agreed programmes and deliver regulatory decisions in predictable timescales

It was also considered by some respondents that any goal-setting system would need to recognise the safety benefits of standardisation as well as the more general disbenefits of potentially making nuclear plant unnecessarily complex.

On a more general level, one respondent expressed concern that the potential advent of a number of new operators may require HSE to expand its resources and manpower to pursue a more "hands-on" approach consistent with IAEA standards and with any EU standards that may yet be introduced.

Role of public in accepting cases

There is a general consensus that a modern approach to licensing should involve the public as key stakeholders through the pre-licensing and public inquiry phases via multiple engagement. There is a divergence of views however over the manner in which this should be undertaken. Some respondents considered that the end of pre-licensing and issue of some form of authorisation would preclude the raising of key issues previously addressed in a public inquiry. Other respondents were equally keen that whether or not an issue is discussed at a pre-licensing meeting it should still be part of the Public Inquiry and not defined out of the proceedings

One common theme is the need for improved publicising of information on proposed designs in the public domain as part of the whole process from pre-licensing through to full operation.

Some correspondents expressed concern over the potential for a long and protracted process. This included some suggestions that the public engagement process should be streamlined in such a way that the total duration of the pre-licensing to granting of a full licence can be reasonably enveloped.

Changes to regulatory approach

There is a general consensus that a greater degree of public engagement is required of a modern regulator. There are a wide variety of suggestions over the extent, depth and timing of this involvement however.

A common suggestion was along the lines that

"Crucial documents such as safety guidelines, safety cases, reference design, preliminary safety report and pre-construction safety report and contract design should all be available at the various points at which they are first produced with a suitable period set aside for the public to obtain their own technical assessment of the documents. Non-technical summaries may be required to assist the process"

A number of respondents were keen for NII to adopt international safety standards. It was also noted that having the *"revised NII SAPs are in place in sufficient time to enable familiarisation and bed-in prior to any new build application"* was important. Publication of the Technical Assessment Guides (TAGs) to support the SAPS was also seen as important.

Another common theme amongst a number of respondents was the importance of giving stability via a reduction in regulatory risk by separating the various aspects of licensing into key stages, which were to some degree *"Bankable"*. It was recognised however that *"as long as a framework is associated with this approach, an adequate resource base is maintained within HSE and transparency is preserved by seeking public input, confidence of the public and the utilities should be sustained"*.

Features of overseas systems to adopt?

It was noted by a number of respondents that the use of a pre-licensing approach was the clearest example of overseas approach that would be useful; the USNRC approach being the most often quoted.

Concern was expressed that

"overseas regulatory systems should add to, not detract from, involvement of the public in reactor licensing and planning".

There was strong support for the existing goal setting regime, a common message being that “This regime offers flexibility for reviews of new reactor designs and may encourage inter regulator exchange of knowledge to mutual benefit.”

From a resourcing perspective it was felt by some respondents that

“The use of technical support organisations facilitates strategic decision making by the main regulatory body and eases resource requirements for the regulator”

8.3 NII Commentary on responses

Once again, there is a strong theme of public engagement in the pre-licensing and subsequent processes.

Support for the UK regulatory goal-setting regime remains strong.

There are a number of comments that suggest that elements of overseas approaches could be adopted within the UK. There may be aspects of good practice that can enhance our regulatory capability and reputation. It must be recognised that first and foremost, NII has to undertake their work within the current UK regulatory (legal) framework and that any perceived deviation from this could be seen as a weakening of standards.

NII intend to have the new Safety Assessment Principles (SAPs) in place prior to any pre-licensing submissions. These provide the framework against which any new design would be judged. Technical assessment guides to support the SAPs will be available shortly after the SAPs are finalised. The SAPs have been benchmarked against what is seen as best international practice.

Annex 2 of the HSE expert report includes a discussion on the new SAPs and the IRRT as drivers to update our processes, including the proposed pre-licensing process.