

NUCLEAR SAFETY DIRECTORATE - BUSINESS MANAGEMENT SYSTEM		
SITE INSPECTION AND ENFORCEMENT PROTOCOL FOR THE SHADOWING OF LICENSEE'S AUDIT ARRANGEMENTS		INS/029
		ISSUE 002
Approved By: <i>R A Powell</i>	R A Powell	Issue Date: 24/10/2005
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1. Purpose and scope

1.1 The purpose of this document is to detail the means by which Inspectors (later referred to as NII Inspector) in all Divisions, but principally the unit responsible for quality assurance expertise, monitor the effectiveness of licensees' auditing arrangements.

1.2 Site Licence Condition 17 requires, amongst other things, the licensee to make and implement adequate quality assurance arrangements in respect of all matters which may affect safety. An integral part of this is the requirement to carry out audits to check compliance against all Licence Conditions. In addition, one of the findings of the Piper Alpha inquiry report (the Cullen Report) was that a regulator should, at the very least review the adequacy of a duty holders auditing process. Therefore the NII intends to carry out, as part of its regulatory activity, shadowing of licensees' audit processes.

2. Policy

2.1 The NII shadowing process is designed to observe the audit techniques employed by the licensee, to witness the way in which the audit is carried out and to monitor the manner and systems employed in raising and recording findings. Of particular importance is the focus and understanding of the audit teams with regard to the significance of findings, the application of any sanction process used by the audit teams and the retention of records of close out.

2.2 This protocol is applicable to the monitoring of licensees' auditing, including internal audits carried out by site staff, those conducted by corporate functions and audits carried out by the licensee on third parties.

3. Definitions

None

4. Procedure

4.1 The unit responsible for quality assurance expertise will seek to obtain the audit programmes of all licensees, on a yearly basis. The licensee should be requested to inform NII when significant changes to the programmes are made.

4.2 In conjunction with the relevant site inspector, particular audits to be shadowed are identified from each of the programmes.

4.3 As part of a planned programme of "inspections", it is envisaged that the major licensees will be subject to at least one shadowing activity in any two years on a rolling basis, or more frequently if circumstances require or Site Inspectors request this.

4.4 The programme of shadowing activities will be subject to a six-monthly review as part of the existing unit strategy review.

4.5 The shadowing activity shall be the observation of the execution of the audit and reporting on audit performance and effectiveness.

4.6 The NII Inspector will advise the licensee concerned prior to the date of shadowing activity to confirm the audit date and make administrative arrangements.

4.7 In the case of a third party audit, the NII inspector shall ask the licensee to explain to the third party the reason for the intended presence of the NII inspector.

4.8 Where possible, a copy of the licensee's audit programme specific to the audit to be shadowed shall be obtained for NII planning purposes.

4.9 Where more than one licensee's auditor is involved in the audit, the NII inspector should consider apportioning the time spent with some or all of the auditors accordingly.

4.10 The NII inspector should attend the opening and closing meetings, auditors' private meetings and the audit activity proper. In the event that the audit is greater than one day in length, the Inspector shall make a judgement on the number of days to attend whilst satisfying the need to observe the main elements of the audit. The NII inspector should observe the process but not take part in the audit.

4.11 During the shadowing process, the NII inspector is expected to use the form at Annex A, to note specific characteristics of the process. The resulting information and the experience and judgement of the NII inspector will ultimately be used to assess the overall effectiveness of the auditing arrangements.

4.12 Following the audit closing meeting, the NII inspector will provide feedback to the licensee's auditor(s) and identify any perceived weakness and/or discuss potential improvements. Good practice will also be commented on.

4.13 Any audit findings that indicate that compliance with Site Licence Conditions is threatened or inadequate will be specifically identified and the appropriate Site Inspector informed.

4.14 A short report of the shadowing activity will be forwarded to the licensee within two weeks of the completion of the activity, which shall include any actions requiring corrective action from the licensee. This framework for this report should be the completed Annex A form, with comments of the NII Inspector against the major headings.

5. Associated Documents

5.1 The NII inspector carrying out the shadowing activity should ensure that the following records are retained on the appropriate file(s):

- 1) Notes of discussions with the relevant site inspector.
- 2) Completed **Annex A form.**
- 3) **Final report to licensee.**
- 4) **Corrective Actions (proposals, correspondence etc.)**

Annex A – Shadowing Activity

TO BE COMPLETED BY SHADOWING INSPECTOR

Licensee:

Location:

Audit type: corporate / site*

Area under audit

Subject of audit

Auditor(s):

Date of Shadowing Activity:

Shadowing Inspector: (name)

..... **(signed)**

..... **(date)**

*** delete as appropriate**

Annex A – Shadowing Activity

CRITERIA	YES/NO	COMMENTS
1. Audit Preparation		
1.1 Does the programme from which the audit was selected seem reasonable in coverage and periodicity i.e. Does it cover important / core aspects over a 3 year period?		
1.2 Has a specific programme for this audit been prepared?		
1.3 Are the scope and objectives of the audit specified?		
1.4 Is the programme realistic? Are there sufficient auditors/timescales		
1.5 Has notice of the audit and programme been given to the auditees?		
1.6 Does the audit programme cover corrective action reports from previous audits?		
1.7 Have question sets/aide memoire been prepared?		
1.8 Are these generated by auditors or pre-authored and provided?		
1.9 Are auditors competent (SQEP)?		
2. Opening meeting		
2.1 Does an opening meeting take place?		
2.2 Is this brief and to the point. Does it identify the process to be followed?		
2.3 Were the attendees at the opening meeting of appropriate level in organisation?		
2.4 Did the Licensee explain the attendance of the NII inspector?		
3. Audit process		
3.1 Has background information been assessed? (procedures, previous audits etc)		
3.2 Is the level of questioning appropriate?		
3.3 Is the selection of personnel (including sample size) for questioning appropriate?		
3.4 Are the question sets/aide memoire used (if prepared)?		
3.5 Is the auditing reactive to the information received, or merely following question sets?		
3.6 Is the style of communication/questioning constructive, informative – or negative?		
3.7 When a non conformance is identified, how is this treated?		
3.8 What is the level of non conformances? (trivial/major etc)		
3.9 Is advice for correction given?		
3.10 Check corrective action status of a recent audit to ensure the process of follow up is established		

Annex A – Shadowing Activity

CRITERIA	YES/NO	COMMENTS
4. Audit Team Review		
4.1 Are auditors private meetings held?		
4.2 Are these brief and useful, with meaningful outcomes?		
4.3 Was the programme adhered to?		
4.4 Did the audit concentrate on compliance only, or give scope for improvement too?		
4.5 Is the basis for the non conformances sound?		
5. Closing meeting		
5.1 Was a closing meeting held?		
5.2 Were the attendees at the closing meeting of appropriate level in organisation?		
5.3 Did the closing meeting note all findings of the audit?		
5.4 Were all findings clearly explained and understanding/acceptance of auditees gained?		
5.5 Was the follow up process and requirements of the auditees explained?		

Overall effectiveness of audit / areas for improvement

Shadowing Inspector: (name)

..... (signed)