



**North East and  
North Cumbria**

## **Integrated Care Board**

# **Pharmaceutical Services Regulations Subcommittee (PSRC) Terms of reference**

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## Establishment

The Pharmaceutical Services Regulations Subcommittee (PSRC) is a Subcommittee established by the Executive committee, in accordance with the NHS North East and North Cumbria's (hereafter referred to as the ICB) Scheme of Reservation and Delegation (SoRD) and Constitution.

The PSRC holds only those powers as delegated in these terms of reference (as defined by the Pharmacy Manual (Version 2, 10 February 2023) and approved by the ICB Board.

## Terms of reference:

**Definition of terms:** The terms of reference are defined by the ICB.

**Amendment:** The terms of reference may be amended in accordance with the provisions set out in this SOP (Establishing Subcommittees).

**Publication:** The terms of reference will be published in the ICB's Governance Handbook which is accessible here:

<https://northeastnorthcumbria.nhs.uk/about-us/corporate-information/governance/>

## Purpose

The purpose of the Subcommittee is to support the Executive Committee to discharge its duties relating to receiving and determining, on behalf of the ICB, applications submitted under the NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013 as amended ('the Regulations').

## Roles and responsibilities

This section describes the Subcommittee's duties, authority, accountability and reporting.

## Duties

The responsibilities of the subcommittee are defined Under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 and will be authorised by the ICB Board. It is expected that PSRC will:

- a. Determine those applications and notifications received under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the 2013 Regulations)
- b. Take overall responsibility for resolving issues of non-compliance with the terms of service as set out in the 2013 Regulations by pharmacy and dispensing appliance contractors;
- c. Make decisions on whether an essential small pharmacy local pharmaceutical services (EPSLPS) contract is to be terminated in line with the provisions of the contract

- d. Health and Wellbeing Boards are responsible for identifying current or future needs for, or improvements or better access to, a pharmaceutical service or pharmaceutical services in general via the pharmaceutical needs assessment (PNA). The PSRC is required to review the PNAs in its area and to record the actions taken to address identified needs, improvements or better access whether this is via the market entry process or through local commissioning processes.

Delegated authority is given to the nominated Primary Care Contract Manager (PCM) to determine those applications and notifications delegated in the regulations. Where necessary the nominated PCM may escalate an application of notification to the PSRC. If, due to annual or sick leave, the nominated PCM is unable to determine an application or notification with the regulatory timescale it is to be determined by the PSRC.

## Authority

<b>The Subcommittee is authorised to:</b>	
<b>Investigate</b>	Investigate any activity within its terms of reference.
<b>Seek information</b>	Seek any information it requires within its remit, from any employee or member of the Board.
<b>Investigate</b>	<p>Commission reports required to help fulfil its obligations from NECS.</p> <p>Commission reports required to help fulfil its obligations from Audit One or the ICB's external auditors, in consultation with the Chief Finance Officer</p> <p>Commission other external reports required to help fulfil its obligations, subject to the financial limits of the most senior member of the Subcommittee.</p>
<b>Obtain advice</b>	Obtain independent professional advice and secure the attendance of advisors with relevant expertise to fulfil its functions. In doing so, the Subcommittee must follow any procedures put in place by the ICB for obtaining professional advice.
<b>Create Groups</b>	Groups may be established by the Subcommittee, but they have no formal status. They do not have any delegated authority from the Board. Their decision making is restricted to decisions and limits of individuals as set out in the ICB's Financial Limits and Financial Delegations. These may not be aggregated and therefore the limits are those of the most senior member present at any meeting of the group. Groups may be permanent or task and finish groups.

## The Subcommittee is authorised to:

### Delegation by Scheme of Reservation & Delegation (SoRD)

Please see Appendix 3

### Accountability and reporting

The subcommittee is accountable to the ICB through the Executive Committee. The minutes of meetings shall be formally recorded and submitted to the Primary Care Strategy and Delivery Subcommittee and then onward to the Executive Committee, in private or public as appropriate.

The Chair of the PSRC shall report to the Primary Care Strategy and Delivery Subcommittee after each meeting and provide a report on assurances received, escalating any concerns where necessary.

The PSRC, through its reports and minutes to the Executive Committee and via the Primary Care Strategy and Delivery Subcommittee, will advise on the adequacy of assurances available and contribute to the ICB's Annual Governance Statement.

Accountabilities	Description
<b>Draft minutes and reports</b>	The secretary formally records the minutes of each meeting. Approved minutes will be provided to the parent committee after each meeting, providing assurances on the business considered and escalating any concerns, where necessary.
<b>Monitor attendance</b>	Attendance is monitored and profiled as part of the agenda at each subcommittee meeting. Members should aim to attend at least 75% of meetings and read all papers beforehand.
<b>Cycle of business</b>	In order to aid agenda planning, the subcommittee may produce an annual work plan and cycle of business in consultation with its parent committee.
<b>Continuous improvement</b>	The subcommittee utilises a continuous improvement approach in its delegation. Members review the effectiveness of the meeting at each sitting.

### Committee meetings

This section sets out meeting:

- Composition and quoracy

- Frequency and formats
- Procedures

## Composition and quoracy

This section sets out the meeting composition and quoracy requirements.

Composition/ quoracy	Description of expectations
<b>Chair</b>	Appointed for their specific knowledge skills and experience and suitability. (Note: does not need to be a member of the ICB board)
<b>Deputy Chair</b>	Subcommittee members may appoint a vice chair from amongst the members.
<b>Absence of Chair or Vice Chair</b>	In the absence of the chair, or vice chair, the remaining members present elects one of their number to Chair the meeting.
<b>Membership</b>	<p>The membership (<b>voting members</b>) will include the following or their deputies as agreed with the Chair:</p> <ul style="list-style-type: none"> <li>• Strategic Head of Pharmacy &amp; Optometry Contracting (Chair)</li> <li>• Director of Contracting &amp; Oversight-North who will chair the meeting in the absence of the Chair (Vice-Chair)</li> <li>• Strategic Head of Medicines and Pharmacy</li> <li>• Primary Care Manager (8A role)</li> <li>• One PSRC Lay Member</li> </ul>

Deputies as agreed by the Chair have the same voting rights as those that they are deputising for.

All members of the PSRC must have a good knowledge and understanding of the Regulations to reduce the likelihood of a successful appeal against decisions made. It is essential that members build up expertise in the Regulations and therefore consistency of attendance is expected. Subject to the provision of this paragraph deputies may be appointed.

The following persons will be co-opted to each PSRC but will be **non-voting** members:

- ICB Clinical Advisor (Fitness to Practice)
- NHS England Clinical Advisor (Market Entry applications)

Composition/ quoracy	Description of expectations
	<ul style="list-style-type: none"> <li>• Primary Care Manager(s) (Band 7 role)</li> </ul> <p>Person's ineligible to be voting or co-opted members of a PSRC are listed in Regulation 62 and in paragraph 26(1) of Schedule 2 to the Regulations. All voting and co-opted members must sign a declaration to confirm that they are not barred by virtue of this regulation or paragraph. The Chair can require any co-opted member to leave the meeting before discussion of a matter and not return until the relevant decision has been made. The minutes will record the absences of the relevant voting or co-opted member or members.</p> <p><b>Persons barred from taking part in decision-making on applications for inclusion in a pharmaceutical list or a dispensing doctor</b></p> <ul style="list-style-type: none"> <li>• A person who is included in a pharmaceutical list or is an employee of such a person</li> <li>• A person who assists in the provision of pharmaceutical services under Chapter 1 or Part 7 of the NHS Act 2006</li> <li>• A person who is an LPS chemist, or a person who provides or assists in the provision of LPS</li> <li>• A person who is a provider of primary medical services</li> <li>• A person who is a member of a provider or primary medical service that is a partnership, or a shareholder in a provider of primary medical services that is a company limited by shares</li> <li>• A person who is employed or engaged by a primary medical services provider</li> <li>• A person who is employed or engaged by an alternative provider medical services contractor in any capacity relating to the provision of primary medical services</li> </ul> <p>No Member may take part in a decision if, in the opinion of the remaining voting members, the circumstances set out in paragraph 26(2) of Schedule 2 to the Regulations apply (reasonable suspicion of bias).</p> <p><b>EDI:</b> When determining the membership of the group, consideration will be given to diversity and equality.</p> <p><b>Involvement:</b> In determining membership consideration will be given to the need for a patient and public involvement member.</p>

Composition/ quoracy	Description of expectations
	<p><b>ICS:</b> Membership may be from across the Integrated Care System. However, the balance of membership must sit with the ICB.</p> <p><b>Conflicts:</b> Consideration must be given to material conflicts in the appointment of members.</p>
<b>Attendees and procedure for absence</b>	<p>Only members have the right to attend meetings.</p> <p>Other attendees: The chair may elect to co-opt additional attendees, where it is in the interests of the activities to do so.</p> <p><b>Procedure for absence:</b></p> <p>Where a member or any regular attendee of the Subcommittee is unable to attend a meeting, a nominated alternative may be agreed with the chair.</p> <p>The chair may ask any or all of those who normally attend to withdraw to facilitate open and frank discussion of particular matters.</p>
<b>Quoracy and Procedure for Inquoracy</b>	<p><b>Threshold:</b></p> <p>No business shall be transacted at a meeting unless at least three of the voting members are present two of which must officers from the ICB.</p> <p>In the event that a meeting of the PSRC is not quorate, the Chair can decide that the meeting will progress, but where urgent regulatory decisions are required, they can be made virtually, logged and noted at the next meeting. All other items will be deferred to the next meeting when the PSRC is quorate.</p> <p><b>Absence:</b> Where members are unable to attend, they should agree this with the chair.</p> <p><b>Disqualification:</b> If any member of the Subcommittee is disqualified from participating in an item on the agenda, due to a declared conflict of interest, that individual no longer counts towards the quorum.</p> <p><b>Inquoracy:</b> If the quorum is not reached, the meeting may proceed if those members attending agree, but no decisions may be taken.</p>

## Frequency and formats

This section on Subcommittee meetings describes the meeting frequency and formats.



Frequency/ format	Description
<b>Meeting frequency</b>	<p>The Subcommittee will meet monthly.</p> <p>Additional meetings may be convened on an exceptional basis at the discretion of the Subcommittee chair.</p> <p>The parent committee chair may ask the Subcommittee to convene further meetings to discuss particular issues on which they want the Subcommittee's advice.</p>
<b>Public vs closed</b>	<p>Meetings will be held in private.</p> <p>External Audit, Internal Audit and Local Counter Fraud representatives will have full and unrestricted rights of access to the Subcommittee.</p>
<b>Virtual meetings and extra-ordinary meetings</b>	<p>In accordance with the Standing Orders, the Subcommittee may meet virtually when necessary and members attending using electronic means will be counted towards the quorum.</p>

## Procedures

Procedure	Description of rules and expectations:
<b>Agenda</b>	<p>The Chair will be responsible for agreeing the agenda and ensuring matters discussed meet the objectives as set out in these terms of reference and in line with the general principles for decision making outlined in the Pharmacy Manual (Version 2, 10 February 2023).</p> <p>Members are expected to identify agenda items for consideration to the chair and any meeting papers using the prescribed format at least 5 working days before the meeting.</p>
<b>Conflicts of interest</b>	<p><b>Declarations:</b> All members and those in attendance must declare any actual, potential, or perceived conflicts of interest. This is recorded in the minutes.</p> <p><b>Exclusions:</b> The Subcommittee will follow and apply the ICB's Standards of Business Conduct with regards to the management of conflicts of interest. This means that the chair will consider the exclusion of members and / or attendees from discussion and / or decision-making if individuals have a relevant material or perceived interest in a matter under consideration.</p>
<b>Decision-making</b>	<p><b>Decisions:</b> Decisions are taken in accordance with the Standing Orders and NHS (Pharmaceutical and Local</p>

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Pharmaceutical Services) Regulations 2013 (as amended) are arrived at by consensus.

Where decisions cannot be made by consensus the Chair of acting Vice Chair (through which the ICB Executive Committee delegations are enacted) will agree the course of action

**Fitness to Practice delegated decision making (as outlined in NHS Pharmaceutical and Local Pharmaceutical Services Regulations 2013 point 52):**

Where an applicant is applying to be included in the relevant pharmaceutical list for the first time and the checks on the fitness information reveal no adverse findings and the references are satisfactory, PSRC can nominate an ICB Clinical Advisor, who has the appropriate clinical experience, to make decisions on whether the applicant is suitable to be included in the relevant pharmaceutical list on fitness grounds.

Where the checks and/or references reveal adverse findings, which may lead the application to be refused or deferred on fitness grounds or for the applicant to be conditionally included, PSRC will be required to make the decision on the applicant's fitness.

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<b>Conduct</b>	The Subcommittee conducts its business in accordance with relevant codes of conduct / good governance practice, including the Nolan principles of public life, the ICB Standards of Business Conduct Policy, and other relevant policies / guidance on good and proper meeting conduct for NHS organisations
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## Secretariat and administration

This section describes the functions of the secretariat whose role is to support the Subcommittee in the following ways:

Functions	Description
<b>Distribute papers</b>	Prepare and distribute the agenda and papers in accordance with the Standing Orders following their agreement by the chair with the support of the relevant executive lead.
<b>Monitor attendance</b>	Monitor the attendance of those invited to each meeting and highlight to the chair those that are not meeting the minimum attendance requirements.
<b>Maintain records</b>	Record conflicts of interest, members' appointments and renewal dates. Provide prompts to renew membership and to identify new members where necessary.

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Functions	Description
<b>Minute Taking</b>	Take good quality minutes and agree them with the chair. Keep a record of matters arising, action points and issues to be carried forward.
<b>Support for Chair &amp; Committee</b>	Support the chair in preparing and delivering reports to the parent committee. Take forward action points between meetings and monitor progress against those actions.
<b>Provide updates</b>	Update the Subcommittee on pertinent issues/ areas of interest/ policy developments.
<b>Governance advice</b>	Provide easy access to governance advice for Subcommittee members

## Appendix 1: Approval History

Version	Date	Approved by	Status
V1.0	14 March 2023	Executive Committee	First Issue
V2.0	10 September 2024	Executive Committee	Second Issue

## Appendix 2: Review History

Version	Date	Reviewed by	Changes Required Y/N?	Summary of changes (Once changes are approved Appendix 1 should be updated)
V2	6 August 2024	Head of Corporate Governance	Y	Membership, quoracy and decision making have been amended

**Review date:** August 2025

**Contact:** Head of Corporate Governance

### Document control

The controlled copy of this document is maintained by the governance team in the Governance Handbook, here <https://northeastnorthcumbria.nhs.uk/about-us/corporate-information/governance/>

Any copies of this document held outside of the Governance Handbook, in whatever format (e.g., paper, email attachment), are considered to have passed out of control and should be checked for currency and validity.

### Appendix 3

Regulatory provision	Decision-maker
Regulations 13, 14 and 21A – determination of application (current need)	Subcommittee
Regulations 15, 16 and 21A – determination of application (future need)	Subcommittee
Regulations 17, 19 and 21A – determination of application (current improvement/better access)	Subcommittee
Regulations 18 and 19 – determination of application (unforeseen benefits)	Subcommittee
Regulations 20, 21 and 21A – determination of application (future improvement/better access)	Subcommittee
Regulation 23 – determination of application (application from NHS chemist in respect of providing directed services)	Subcommittee
Regulation 24 – determination of application (relocation involving no significant change)	Subcommittee
Regulation 25 – determination of application (distance selling pharmacies)	Subcommittee
Regulation 26(1) – determination of application (change of ownership)	Officer or Subcommittee
Regulation 26(2) – determination of application (relocation involving no significant change/change of ownership)	Subcommittee
Regulation 26A – determination of preliminary matters including refusal of application for reasons set out in Regulation 26A(5)(b)	Officer
Regulation 26A – determination of application (consolidation onto an existing site)	Subcommittee
Regulation 27 – determination of application (for temporary listing arising out of suspension)	Subcommittee
Regulation 28 – determination of application (exercising right of return to the pharmaceutical list)	Officer or Subcommittee
Regulation 29 – determination of application (temporary arrangements during emergencies/because of circumstances beyond the control of NHS chemists)	Officer or Subcommittee
Regulation 30 – refusal on language requirement for some NHS pharmacists	Subcommittee or Performers List Decision Panel (PLDP)
Regulation 31 – refusal: same or adjacent premises	Subcommittee

Regulation 32 – deferrals arising out of LPS designations	Officer or Subcommittee
Regulation 33 – determination of suitability of an applicant to be included in a pharmaceutical list on fitness grounds	Subcommittee or PLDP
Regulation 34 – determination of deferral of application to be included in a pharmaceutical list on fitness grounds	Subcommittee or PLDP
Regulation 35 – determination of conditional inclusion of an applicant to be included in a pharmaceutical list on fitness grounds	Subcommittee or PLDP
Regulation 36 – determination of whether an area is a controlled locality (or is part of a controlled locality), as a result of a local medical committee or local pharmaceutical committee request for such a determination or because NHS England is satisfied that such a determination is required (and make arrangements for any controlled locality to be clearly delineated on a published map)	Subcommittee
Regulation 37 – process for determining controlled localities: preliminary matters	Subcommittee
Regulation 40 – applications for new pharmacy premises in controlled localities: refusals because of preliminary matters	Subcommittee
Regulations 41 and 42 – determination of whether premises are (or a best estimate is) in a reserved location (and make arrangements for any reserved location to be clearly delineated on a published map)	Subcommittee
Regulation 44 – prejudice test in respect of routine applications for new pharmacy premises in a part of a controlled locality that is not a reserved location	Subcommittee
Regulation 48(2) - determination of patient application ('serious difficulty' applications)	Officer or Subcommittee
Regulation 48(5) to (9) – making of arrangements with a dispensing doctor to dispense to a particular patient or patients	Subcommittee
Regulation 50 – consideration of 'gradualisation' (i.e. the postponement of the discontinuation of services by dispensing doctors) for an application in relation to premises in, or within 1.6km of, a controlled locality	Subcommittee
Regulations 51 to 60 – determination of doctor application (outline consent and premises approval) including the taking effect of decisions, relocations, gradual introduction of premises approval, temporary provisions in cases of relocations or additional premises where premises approval has not taken effect, practice amalgamations, and lapse of outline consent and premises approval	Subcommittee

Regulation 61 – temporary arrangements during emergencies or circumstances beyond the control of a dispensing doctor	Officer or Subcommittee
Regulation 65(5) to (7) – direction to increase core opening hours	Officer or Subcommittee
Regulation 67 – agreement of a shorter notice period for withdrawal from a pharmaceutical list	Subcommittee
Regulation 69 – determination of whether there has been a breach of terms of service	Subcommittee
Regulation 70 – determination of whether to issue a breach notice with or without an accompanying withholding of payments in connection with a breach of terms of service. Determination of whether to rescind a breach notice	Subcommittee
Regulation 71 – determination of whether to issue a remedial notice with or without an accompanying withholding of payments in connection with a breach of terms of service. Determination of whether to rescind a remedial notice	Subcommittee
Regulation 72 – determination of whether to withhold remuneration	Subcommittee
Regulation 73 – determination of whether to remove premises or a chemist from the pharmaceutical list (following remedial or breach notice)	Subcommittee
Regulation 74 – determination of whether to remove premises or a chemist from the pharmaceutical list (death, incapacity or cessation of service)	Subcommittee
Regulation 79 – determination of review of fitness conditions originally imposed on the grant of an application	Subcommittee or PLDP
Regulation 80 – determination of removal of a contractor for breach of fitness conditions	Subcommittee or PLDP
Regulation 81 and 82 – determination of removal or contingent removal	Subcommittee or PLDP
Regulation 83 – suspensions in fitness cases	Subcommittee or PLDP
Regulation 84 – reviewing suspensions and contingent removal conditions	Subcommittee or PLDP
Regulation 85 – general power to revoke suspensions in appropriate circumstances	Subcommittee or PLDP
Regulation 94 – overpayments	Subcommittee
Regulation 99 – designation of an LPS area	Subcommittee
Regulation 100 – review of designation of an LPS area	Subcommittee
Regulation 101 – cancellation of an LPS area	Subcommittee
Regulation 104 – selection of an LPS proposal for development and decision to adopt proposal	Subcommittee
Regulation 108 – right of return for LPS contractor	Subcommittee
Schedule 2, paragraph 1(10) – whether a best estimate is acceptable	Officer or Subcommittee

Schedule 2, paragraph 11(1) – determination of whether there is missing information	Officer
Schedule 2, paragraph 11(2)(b) – determination of review of reasonableness of request for missing information	Officer or Subcommittee
Schedule 2, paragraph 14 – whether to defer consideration of application	Officer or Subcommittee
Schedule 2, paragraph 19 – determination of who is to be provided with notice of a notifiable application	Officer
Schedule 2, paragraph 21(4) – determination of whether the full disclosure principle applies to information contained within a notifiable application	Subcommittee
Schedule 2, paragraph 22(2) – whether oral representations are to be provided and who may be additional presenters as defined in Schedule 2, paragraph 25(2)	Officer or Subcommittee
Schedule 2, paragraph 25 – decision to hold an oral hearing to determine an application	Subcommittee
Schedule 2, paragraph 28 – determination of who is to be notified of decisions on routine and excepted applications	Officer or Subcommittee
Schedule 3, paragraph 30 – determination of who is to have a third party right of appeal against decisions on routine and excepted applications	Officer or Subcommittee
Schedule 2, paragraph 31 – consideration of a notification of address following a 'best estimate' routine application. Where this may lead to a refusal under regulation 31, the matter should be escalated to the committee	Officer or Subcommittee
Schedule 2, paragraph 32 – determination of whether to accept a change to premises	Officer or Subcommittee
Schedule 2, paragraph 33 – determination as to whether the future circumstances have arisen	Officer
Schedule 2, paragraph 34 – decisions as to whether notices of commencement are valid, and whether a shorter notice period can be given	Officer
Schedule 2, paragraph 34A – decisions as to whether notices of consolidation are valid, and whether a shorter notice period can be given	Officer
Schedule 2, paragraph 34(4)(c)(i) and 34A(4)(b)(i) – extension of latest date for receipt of notice of commencement or consolidation	Officer or Subcommittee
Schedule 2, paragraph 35 – notice requiring the commencement of pharmaceutical services	Officer or Subcommittee
Schedule 4, paragraph 23(1)/Schedule 5, paragraph 13(1) – consideration of a request to temporarily suspend the provision of services (fixed period)	Subcommittee



Schedule 4, paragraphs 23–25/Schedule 5, paragraphs 13–15 – decision to direct a contractor to open at certain times on certain days	Subcommittee
Schedule 4, paragraph 23(10)/Schedule 5, paragraph 9 – review of reason for temporary suspension within the control of the contractor	Subcommittee
Schedule 4, paragraph 26/Schedule 5, paragraph 16 – determination of core opening hours instigated by the contractor	Subcommittee
Schedule 4, paragraph 27/Schedule 5, paragraph 17 – temporary opening hours and closures during an emergency requiring the flexible provision of pharmaceutical services	Officer or Subcommittee
Schedule 4, paragraph 27B – flexible provision of relevant immunisation services during a pandemic	Officer
Schedule 4, paragraph 28A – premises requirements in respect of consultation rooms – decisions that a pharmacy premises is too small	Officer or Subcommittee
Schedule 5, paragraph 13(6) – arranging for amendments to be made to the relevant pharmaceutical list following notification of a change of supplementary opening hours (where change is not intended to come into effect sooner than three months after receipt of notification of change)	Officer or Subcommittee
Decisions relating to compliance with the dispensing doctor terms of service	Subcommittee
Approval of responses to an appeal against, or challenge to, decisions of the committee	Officer or Subcommittee
Approval of responses to an appeal against, or challenge to, decisions of the officer	Officer or Subcommittee
Determination of further action where community pharmacy assurance framework identifies concerns	Officer or Subcommittee
Determination of further action where the contractor fails or refuses to agree a date and time for a visit	Officer or Subcommittee
Determination of action where any of the following are identified: <ul style="list-style-type: none"> <li>• patient safety issues</li> <li>• the commissioner is at risk of material financial loss, and/or</li> <li>• possible fraudulent or criminal activity.</li> </ul>	Officer or Subcommittee
Determination of action where the contractor fails to complete the required actions or fails to respond to a visit report	Officer or Subcommittee
Determination of action where the contractor exceeds the maximum number of appliance use reviews that may be done in any one year	Officer