Cefas Protocol for Inspection and Approval of Purification (Depuration) Systems – England and Wales.

Version 9

43 Pages

This protocol describes the work undertaken by Cefas on behalf of the Food Standards Agency. Customer contract reference: C3019A

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GLOSSARY	
Byssal threads	Strong fibres made from protein that are used by mussels and other bivalves to attach to rocks and other surfaces. Also known as the mussel's 'beard'
Depuration	The reduction of micro-organisms to a level acceptable for direct consumption by the process of holding live bivalve molluscs for a period of time under approved, controlled conditions in natural or artificial seawater suitable for the process, which may be treated or untreated.
Depuration plant/centre	Any approved establishment for the depuration of live bivalve molluscs.
***Escherichia coli* (*E. coli*)**	A species of bacterium that is a member of the faecal coliform group. It is more specifically associated with the intestines of warm-blooded animals and birds than other members of the faecal coliform group.
Norovirus	Noroviruses are small, round, 27 to 32 nm diameter, structured RNA viruses which have been implicated as the most common cause of nonbacterial gastroenteritis outbreaks.
Seafish	Seafish Industry Authority Seafish is a Non-Departmental Public Body (NDPB) set up by the Fisheries Act 1981 to improve efficiency and raise standards across the seafood industry

ACRONYMS	
Cefas	Centre for Environment, Fisheries and Aquaculture Science
CoA	Conditions of Approval
Defra	Department for Environment, Food and Rural Affairs
EHO	Environmental Health Officer
EPT	End Product Test
DO	Dissolved oxygen
FSA	Food Standards Agency
FBO	Food Business Operator
ISO	International Organization for Standardization
LEA	Local Enforcement Authority
UKAS	United Kingdom Accreditation Service
UV	Ultraviolet

Foreword

The contents of this generic Cefas protocol, for the inspection and approval of purification (depuration) systems, detail the current practices and approaches employed by the Cefas Microbiological Food Safety Depuration System Inspection Service, in agreement with and as approved by the customer. The contents of this document are under continual review.

Introduction and Scope.

Under Regulation (EC) No. 853/2004 of the European Parliament and of the Council, the approval for shellfish purification plants to operate must be given by the local Enforcement Authority subject to the conditions set out in the Regulations and any additional conditions notified by FSA. In England and Wales, Cefas has the delegated responsibility for setting the specific conditions under which the system should operate. For new systems these "Conditions of Approval" are set following a technical inspection. Similarly, technical inspections may be made where systems have been modified sufficiently to significantly change the design and operation of the system. Further, inspections of existing purification systems may be undertaken at the request of the Enforcement Authority, where changes to the system have taken place; where outbreaks have occurred; or where Microbiological end-product failures have occurred. The FSA also requires Cefas to carry out technical re-inspections for all purification plants in England and Wales at a frequency based on an assessment of risk.

This document sets out the circumstances under which technical inspections of purification systems should be made. It also lays down procedures for performing such inspections so that Conditions of Approval can be written. Cefas has the responsibility for ensuring the system is of acceptable design and construction and is operated correctly. This includes ensuring procedures for collection and treatment of water and shellfish prior to depuration are appropriate. General hygiene issues (including HACCP assessments and traceability) and the operation of the centre such as packaging and dispatch; provision of the washing facilities and cleanliness of the centre are the responsibility of the Local Enforcement Authority (LEA).

Depuration Inspection Criteria

System type and specifications

- mode of action (standard Seafish design or 'novel')

Species depurated

- method of harvesting (suitable for species to be depurated e.g. cockles and razor clams have specific requirements)

Maximum loading capacities

- loading arrangements (must facilitate free and even flow of water)
- tray type

UV specifications

- dose and utilisation (must exceed minimum dose prescribed for comparable standard system of interest or in any event >10mJ/cm^2)
- pre-treatment of seawater (to achieve 'clean seawater')

Flow rate

- flow meter (must be present on all new systems)
- dissolved oxygen levels (should be >5mg/L)

Seawater criteria

- minimum salinity (species dependent)
- minimum temperature (species dependent)
- clarification , turbidity assessment
- UV treatment prior to use (fill via UV or recirculate for 12 hrs)

Minimum period of depuration (42hrs)

Drain down procedures (to avoid resuspension of sediment)

Current Conditions of Approval must be on display or readily available

Record checks

- end product testing (EPT)
- UV usage
- Purification dates and times
- temperature
- salinity
- seawater re-use (where relevant)
- loading density
- flow rate
- species

Details of the specific requirements and recommendations of good practice for the depuration of live bivalve molluscs are given in section 2.5 – 0 and 3.3 – 3.4 of this document.

1 Pre-inspection

A number of situations arise where inspections of a purification system are required and these are listed below:

- New depuration plant
- New type of system differing from existing systems at an approved plant
- Modification to an existing system including relocation and re-installation.
- By invitation from the responsible LEA usually following end-product failures, outbreaks of illness associated with shellfish from the system or change of ownership
- As part of the ongoing re-inspection programme.

1.1 New Systems

New systems fall into one of three categories: standard design systems, systems based on standard design technology and non-standard design systems. If the system is a standard Seafish Industry Authority (Seafish) design the appropriate operating manual may be consulted if required:

- Medium scale multi-layer system
- Large scale multi-layer system
- Small scale shallow tank purification system
- Bulk bin system
- Vertical stack system

Operating manuals exist for the above types of system and electronic copies of these documents can be found on the Seafish website.

1.1.1 Obtaining information from the applicant/ Local Enforcement Authority

All correspondence connected with the approval of purification plants should be with an officer of the Local Enforcement Authority (LEA) responsible for the approval of the purification operation in question. If approached by operators directly Cefas should direct the operator to the appropriate LEA.

Only advice relating to the general requirements for purification systems and the approval process should be given by Cefas. Prospective plant operators should be directed to Seafish, the industry authority for technical information on systems or other competent consultants.

The LEA will notify Cefas of any intended new depuration system, either in a new or an existing plant. Prior to undertaking any further action, including inspection, the officer must obtain as much information as possible on the system, to enable any potential problems to be dealt with before the inspection. This should include:

- Name and contact number of the LEA officer.

- Operators name, address and contact number
- The company name
- Type of system (Small Scale, Medium Scale, Large Scale, Bulk Bin, or Non Standard Design*.
- Plans of the plant and proposed system(s).

NB If of non-standard design, details will be required of the design, construction, plumbing and intended system of operation.*

- Intended shellfish species for depuration.
- Type of seawater intended for use (natural, artificial or both)
- Proposed harvesting area

A 'request to inspect' data sheet together with guidance notes of the Approval process should be sent to the LEA (forms D003 and D004). The data sheet should be completed by the LEA in conjunction with the Food Business Operator (FBO) and returned to Cefas. Where copies of system specification and plans are available these should also be obtained. LEAs should be asked to obtain all of this information. A request for pictures of the system(s) should also be made. Such information should be sent by post or e-mailed by the LEA to Cefas.

NB. The Regulations require an applicant to provide the LEA with such information as is necessary to enable it to fully assess the application.

The return of the completed form is normally a good indication of readiness to inspect. On receipt of the completed form, the LEA should be contacted and a visit arranged.

If the system is an addition to an existing purification centre information obtained should be placed on the appropriate existing file. If the system is part of a new purification centre, a new Cefas file should be opened.

1.1.2 Microbial Testing

All new purification systems require microbiological testing to demonstrate their ability to eliminate bacteria. It should be noted that this forms only one part of the approval process. It is these results in conjunction with other information gathered during the inspection of the system, which ultimately determine whether Conditions of Approval should be issued. Procedures for this are described in Part 4 of this protocol. Inspections of new systems should, where possible be planned to coincide with the microbiological test. Ideally, inspections should coincide with the termination of the depuration process so that the fully functioning system can be assessed and an assessment made of the 'drain-down' procedures.

1.1.3 Informing LEAs of Requirements for Inspection of New Systems

Prior to making an inspection it is important to inform the LEA officer of Cefas's requirements during an inspection.

- New systems must be fully loaded (preferably with the main species to be purified) at the time of inspection. If systems are not fully loaded Conditions of Approval can only be written to permit the operation of the system at loading densities observed during the inspection.

- If more than one new system of the same design is present at the plant it is only required to microbiologically test one. In such cases it should be confirmed during an inspection that the systems are actually of the same design and construction (especially plumbing).

- Details of requirements for microbiological testing of the system are given in part 4.

Standard documentation (forms D012 and D013) setting out these requirements has been prepared and should be sent to the LEA. This documentation may be amended as required for specific situations.

All correspondence sent and information obtained prior to the inspection must be placed on the appropriate file.

1.1.4 Approval of additional system(s) identical to existing system(s) in an approved premises

If the FBO already has at least one of the same type of system already approved at the plant, then approval of any new identical systems may be able to be performed without a Cefas site inspection. The following criteria must be met for a site visit not to be considered necessary:

- Application relates to a Seafish standard design system
- Food Business Operator (FBO) already has at least one of the same type of system already approved with no history of problems in relation to challenge testing, operation of the system or end product testing
- FBO is considered to be fully competent
- LEA is confident that a Cefas site visit is not necessary

The final decision on whether a site visit is necessary will be made by Cefas in conjunction with the Local Enforcement Authority (LEA). A full microbiological challenge is not required, but we would request that the first 3 cycles are end product tested and results forwarded to Cefas when they are available

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1.1.5 Modified Systems (including those relocated or re-installed)

It is a requirement of the Conditions of Approval for all systems, that any proposed modifications to an approved system must be notified to the LEA. The LEA should notify Cefas of the owner's intentions before work is undertaken.

Sufficient information should be obtained from the LEA including, where possible, photographs to assess the possible implications of the modification(s). If the proposed modification(s) are considered by Cefas to potentially significantly change the design or operation of the system, it will be necessary to inspect the system to ensure the modification(s) is (are) acceptable. For tanks that have been re-installed in the premises an inspection may be required to ensure that all systems have been re-installed correctly and that there have not been any other changes.

All information regarding the modification must be placed on the appropriate file.
It is for a trained Cefas officer, in conjunction with the LEA, to decide whether a further inspection is warranted. If a decision is made not to undertake an inspection, the reason for this must be placed on the appropriate file and the database updated as appropriate.

Further microbiological testing of modified system(s), as described in Part 4 of this protocol, may be required if doubt over the effect of the modification exists.

Where systems are moved to new premises an inspection of the system(s) must be made and a post-depuration microbiological end product test carried out. Where multiple systems of the same type are moved, a single microbiological assessment of one of the systems will suffice.

1.2 Approved systems.

1.2.1 Routine Re-inspections

A programme of depuration plant re-inspection was established in 1998. Purification centres are selected for inspection on the basis of the risk based scoring system (SOP 1287 Risk Assessment Based Selection for Re-inspection Programme).

Centres representing the highest risk will be inspected every 2 years; those representing the least risk every 4 years and those with an intermediate risk every 3 years. It should be noted that as many of the factors that will go towards making up the plant's assessment will vary from year to year (e.g. outbreaks, end product failures, non-compliances) the score for each centre may vary annually.

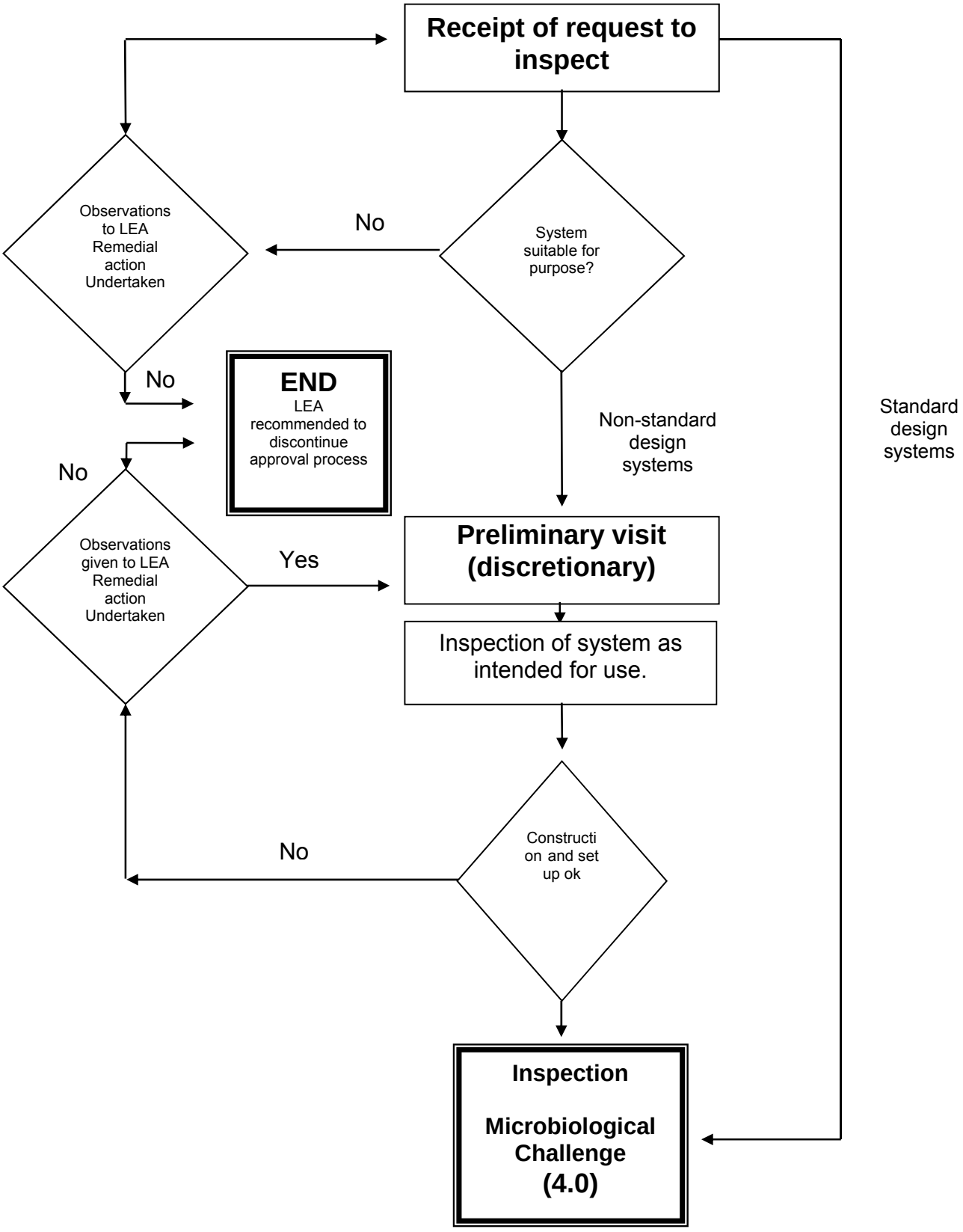
1.2.2 Outbreaks, End-product Failures & Inspection Requests from the LEA

If the inspection is not part of a routine re-inspection programme, as much information as possible should be gathered from the LEA regarding the reason for the request. For example, dates of any outbreaks or end-product failures should be ascertained and/or details of unusual events such as system failures or heavy rainfall in the harvesting area. Such information should be assessed before an inspection as this may help to identify reasons why poor results or outbreaks have occurred.

Some pertinent questions which could be asked before the inspection are;

- Was there any unusual weather associated with the harvesting area at these times?
- Has the source of shellfish purified changed?
- Are movement documents available?
- Dates of outbreaks and end-product failures (if any)?
- Have there been any system failures (pumps, UV etc.)?
- Are there any new staff at the centre?
- Is the centre supplying new markets/customers?

Figure 1. Flow of events following receipt of the 'Request to Inspect' data sheet.



1.2.3 Re-inspections

Re-inspections should be carried out on fully loaded systems, preferably towards the end of the cycle when procedures for draining down can be observed. If this is not possible then inspection should be at least 12 hours into the cycle. For systems that demonstrate continued problems, it may be necessary to make observations at a number of stages during a 42 hour depuration cycle.

For all re-inspections it is important to ask the relevant LEA to liaise with the operator to ensure that all records and microbiological results are available during the inspection.

Before any re-inspection the appropriate site file should be consulted and notes made of any unusual features or conditions that apply to the system.

If the system is a standard Seafish design the appropriate operating manual may be consulted for general information on the intended dimensions, construction and mode of operation. Electronic operating manuals exist for the following types of system and these can be found on the Seafish website.

- Medium scale multi-layer system
- Large scale multi-layer system
- Small scale shallow tank purification system
- Bulk bin system
- Vertical stack system

1.2.4 Informing LEAs of Requirements for Re-Inspection

Prior to making an inspection it is important to inform the LEA officer of Cefas's requirements during an inspection.

A standard letter template (D014) regarding the requirements for re-inspection has been prepared and should be sent to the LEA as confirmation of the intended visit. This letter may be amended as required for specific situations.

All correspondence sent and information obtained prior to the inspection must be placed on the appropriate file.

2 Inspection and Re-inspection Procedures

2.1 Safety

The size and standard of depuration plants vary considerably as do the risks to personal safety. Heavy machinery and/or vehicles such as forklift trucks may be used on site. Floors are often wet and may be slippery. Overhead obstacles may lead to head injuries. Wear suitable clothing especially in winter when extra warm clothing may be required for long periods of standing in the tank rooms. Ensure footwear has sufficient grip on wet surfaces to avoid injury due to slipping etc. Appropriate advice produced by the accompanying LEA officer or the operator should be taken into account.

Before performing inspection procedures staff should have read and understood the relevant COSHH & risk assessments. When arriving on site, staff should first undertake a dynamic personal risk assessment and make a note of any potential hazards on the inspection sheet. Appropriate action should be taken to address any identified hazards. In extreme cases, if the staff member feels that appropriate remedial action cannot be taken and feels it is unsafe to proceed, then the inspection should not be undertaken until the identified issue(s) has been satisfactorily addressed..

2.2 Biosecurity

It is essential that the Cefas inspectors implement and uphold stringent biosecurity measures to prevent the risk of the potential spread of shellfish disease in the field or laboratory. Inspectors must read SOP 2211 Depuration Plant Inspection Service Biosecurity Measures and ensure that their activities do not result in the spread of pathogens of shellfish.

2.3 Training

Trainees must read this Protocol and associated SOP's.

Officers should attend at least 2 purification plant inspections with an experienced member of staff to allow sufficient familiarisation with the overall process of inspection before carrying out an inspection on their own.

Due to the need for on-site measurements to be taken, officers should be trained in the use of the dissolved oxygen meter, refractometer, turbidity meter, flow meter, GPS and digital camera. Advice should be sought from experienced officers where necessary.

2.4 Equipment

The following equipment is required for inspection purposes.

- Maps -'Landranger' maps can be used for ascertaining location of seawater abstraction (if natural seawater is used) and location of purification centre. Global positioning system (GPS) devices are also available for this purpose.

- Tape measure, flow meter, refractometer, oxygen meter including electronic thermometer, calibrated temperature probe, turbidity meter and digital camera.

All equipment should be regularly maintained and calibrated as necessary according to Cefas SOP 1285 Measurement and Calibration.

2.5 Inspection Procedures

Purification plant inspections should only be undertaken in the presence of a representative from the LEA.

During the site inspection a depuration inspection record sheet (Form D001) should be completed to act as a prompt to undertake the necessary assessments and to record relevant information. The following sequence of events can be taken as a guide to the inspection procedure although each inspection may be different and the inspector will need to use considerable personal judgement regarding completion of any given inspection.

- Confirm the name of the operator, the company name and the address. Mark the position of the premises on a map to obtain an 8-figure grid reference. Where there is uncertainty over the exact location exists a GPS may be used to obtain a grid reference.

- Ascertain the time and date the purification cycle started and if there have been any problems. These should be recorded.

- The operator and EHO should be briefed at an appropriate point during the inspection on the requirements for record keeping.

The following points 2.5.1 - 2.5.6 represent the minimum information that should be gathered during the inspection:

2.5.1 Seawater Quality

For information on seawater quality please refer to section 3.3.3.

- Determine whether natural or artificial seawater is used or intended to be used.

- Ascertain where natural seawater is collected and mark this point on a map to obtain an 8-figure grid reference. Where there is uncertainty over the exact location, a GPS device may be used to obtain a grid reference. Establish if any microbiological/chemical analysis of seawater from the proposed extraction point has been undertaken.

- Ascertain whether any pre-treatment (settlement or filtration) is undertaken and confirm whether the system is filled through an operational UV or instead whether seawater is recirculated through the operational UV for a minimum of 12 hours before shellfish are added (based on 1:1 mixing and a minimum flow rate of one full water exchange per

hour). If settlement/pre-treatment is required a brief description of the method, including manufacturer's details of filtration instrument, where relevant, should be added to the Conditions of Approval document .

- Ascertain whether seawater is re-used, or intended to be re-used for more than one purification cycle. If so, ensure there is adequate capacity of seawater storage facilities to hold seawater between cycles. Ensure that storage facilities are cleanable and allow drainage. Ensure drainage of the depuration tank is set up to allow water from the depuration tank to be transferred to the storage tank without sediment also being transferred (Seawater re-use 3.3.3.1).

2.5.2 System

- Ensure that the system is of sound construction with no leaks and that all associated plumbing is of sturdy construction. Tanks and plumbing should be of a material, which is easy to clean, and non-toxic.

- Ensure that the system is self-contained with no sources of external contamination i.e. if the system is outside it must be covered.

- Ensure circulation of water in the system is even throughout the entire system with no apparent possible dead spots.

- Determine whether cascades interfere with shellfish activity i.e. fall directly on to shellfish.

- Determine if any supplementary aeration is present and if so whether it interferes with shellfish activity.

- Ensure that the trays/baskets used in the system are of a suitable design. (i.e. Approved trays, Table 5). Ensure that the trays/baskets are stacked in a stable condition and are raised of the base of the tank to prevent re-contamination by sediment.

- Determine the basket/tray loading arrangements do not interfere with the flow of water in the system.

- Determine whether shellfish are loaded in trays to a suitable capacity/depth.

- Ascertain the number of basket/trays in each system and their dimensions. This information is used to determine the shellfish capacity of the system with reference to Table 3.3.

- Ensure that all shellfish are totally covered with seawater.

- Determine the internal tank dimensions and water depth*.
  (This is used to calculate the water volume of the system).

NB For stacking systems the volume within the system calculated will include tank and tray dimensions and water depth.*

- Inspect the UV system and ensure that it is operational, meets the minimum applied UV dose requirement (see point 3.3.2.3) and is (as far as can be seen) in a clean state. Record the manufacturer's details and power rating.

2.5.3 Measurements

During the inspection measure the following parameters using equipment according to the manufacturer's manuals;

- Tank dimensions and water depth.
- Seawater temperature. Compare with acceptable minimum temperatures in Table 1.
- Flow rate either directly using flow meter in system or with Cefas non-invasive meter or both if tank flow meter is suspected of not being accurate.
- Seawater salinity. Compare with acceptable minimum salinities in Table 1

N.B. Seafish good practice guidance recommends that the salinity of the depuration water should be within 20% of the area from which the shellfish were sourced.

- Dissolved oxygen levels should be measured at a minimum of three places in the tank usually at the spray bar, middle of the system and at the suction bar.
- The minimum D.O. at any point in the tank must be capable of sustaining normal physiological activity of the shellfish. D.O should be expressed in absolute terms (mg/l) and not % saturation as temperature and salinity have a profound effect on absolute D.O. (Table 2). The minimum D.O. value currently used by Cefas in assessing the oxygenation capabilities of depuration systems is 5mg/l.

Table 1. Minimum specified salinities and temperatures for depuration.

	Minimum Salinity (‰)	Minimum Temperature (°C)
Pacific Oysters (*Crassostrea gigas)*	20.5	8
Native Oysters (*Ostrea edulis*)	25.0	5
Mussels (*Mytilus* spp.)	19.0	5
Cockles (*Cerastoderma edule*)	20.0	7
Hard clam (*Mercenaria mercenaria*)	20.5	12
Native clam (*Tapes decussatus*)	20.5	12
Manila clam (*Tapes philippinarum*)	20.5	12
Razor clams (*Ensis* spp.)	30	10
Scallops (*Pecten maximus*)	35	10
Thick trough shell (*Spisula solida*)	30	12
Peppery furrow shell (*Scrobicularia plana*)	20.5	12
Sand gaper (*Mya arenaria)*	25	10

Table 2. Absolute dissolved oxygen (mg/l) in seawater (35 parts per thousand – ppt or ‰) for a range of temperatures, as compared with % dissolved oxygen.

Temperature	% Dissolved Oxygen (D.O.)					
^{0}C	100	90	80	70	60	50
5	10.0 mg/l	9.0 mg/l	8.0 mg/l	7.0 mg/l	6.0 mg/l	5.0 mg/l
10	9.0 mg/l	8.1 mg/l	7.2 mg/l	6.3 mg/l	5.4 mg/l	***4.5 mg/l***
15	8.1 mg/l	7.3 mg/l	6.5 mg/l	5.7 mg/l	***4.9 mg/l***	***4.0 mg/l***
20	7.4 mg/l	6.6 mg/l	5.9 mg/l	5.2 mg/l	***4.4 mg/l***	***3.7 mg/l***
25	6.8 mg/l	6.1 mg/l	5.8 mg/l	**4.2 mg/l**	***4.0 mg/l***	***3.4 mg/l***

2.5.4 Operation

Ascertain from the operator the procedures that are used during the operation of the system.

NB Ask the operator to describe the process employed from start to finish. Observe as much independent evidence of the practices as possible.*

Actions described should conform to the following:

- Shellfish should be thoroughly cleaned (without immersion) and placed into approved trays. Trays should be stacked in the tank in an appropriate configuration (i.e. to ensure even flow of water throughout the tank) and should be raised off the base of the tank by a minimum of 25mm for small-scale systems and 50mm for medium/large-scale systems. In vertical stack systems, shellfish should be raised off the floor of trays by a minimum of 15mm (the mesh insert provided normally achieves this). The tank should then be filled with seawater via the operational UV system. Alternatively water may be pumped directly into the tank and recirculated via the operational UV unit for a defined period before adding baskets of shellfish to the system.

- Purification must be for a minimum continuous period of 42 hours (*Mya arenaria* may require longer) without disturbance to the shellfish. No shellfish should be added to the purification tank during the cycle. During that time shellfish must remain completely immersed in water.

- Following completion of the cycle, seawater should be drained from the tank to below the level of the shellfish in the bottom layer without disturbing the shellfish. Subsequently shellfish should be removed from the tank and thoroughly cleaned (without immersion) with potable or clean seawater.

- Ensure tanks are cleaned thoroughly between cycles.

- Ensure procedures are in place for storing water between purification cycles if water is re-used.

2.5.5 Shellfish

- Ensure all shellfish are clean, alive and healthy and appear to be actively filtering.

- Determine the method of harvesting and ensure that this is appropriate for the species of shellfish depurated (e.g. currently razor clams and cockles may only be depurated if hand-gathered).

- Determine whether shellfish are loaded to the correct depth.

2.5.6 Advice

If the system is found to be defective or in breach of the Food Safety Regulations, it is important not to offer specific advice on how the situation should be rectified as this may compromise the position of Cefas should the advice be taken up but the fault still not rectified. While general guidance can be given on the requirements for depuration, specific engineering solutions must not be offered. Instead, operators should be directed towards Seafish or other suitable consultants.

2.5.7 Impartiality

To comply with ISO 17020:2012 and Civil Service Policy it is necessary for the Cefas depuration plant inspection service to operate in an impartial manner and to monitor on an ongoing basis any potential 'risks' to impartiality to ensure that this is maintained.

2.6 Re-inspections

2.6.1 Record keeping

Minimum requirements for keeping records are:

- Displaying or having readily available the current CoA document(s)..
- Time, quantity and species of shellfish in and out of the tanks.
- Microbiological results before and after depuration on a number of purification cycles.
- UV usage / lamp replacement
- Water reuse in exceptional circumstances

Operators should also be encouraged to keep the following record for good practice and due diligence purposes:

- Seawater temperature.
- Seawater salinity.
- Flow rates.
- Tank cleaning.
- Water re-use.

2.6.2 Non-compliance

Judgement in determining what constitutes a major or minor non-compliance will be required. However some examples are given below:

- Major – poor maintenance, inadequate seawater treatment, not keeping required records, significant operational problems (draining down, batch operation), and significant modifications without informing Cefas.

Minor – slight overloading of shellfish, not keeping due diligence records.

2.6.3 Onsite discussion of findings

During the inspection it is important to point out any deficiencies that are observed to both the operator and the LEA representative. The reasons why these represent a problem should be explained. It is helpful to make a note of any unusual features or problem areas and to make sketches and take photographs if appropriate to aid the information of other officers. General photographs of the tank layout, plumbing and UV system should be taken for the file.

3 Post inspection

3.1 New systems

With reference to data gathered during the inspection process, determine whether the system meets the requirements for depuration. If necessary, refer to existing Seafish manuals for standard designs held electronically in the depuration folder and other relevant documentation.

If shortfalls in the systems operation or design are identified a letter should be sent to the LEA outlining the identified problems. A clear distinction must be made between those shortfalls that constitute non-compliance with the Conditions of Approval or standard purification requirements and recommendations of best practice. This letter should be sent as soon as possible and within 10 working days of the inspection. This letter must be copied to the Food Standards Agency.

Conditions of Approval must not be sent to LEAs until the system fully meets the usual minimum requirements for depuration (as described in this protocol). Where problems have been encountered, this may involve a re-inspection or at least written confirmation from the LEA that the problem has been dealt with.

If the system meets the minimum requirements for depuration systems, write Conditions of Approval for the system, using the standard template. This should then be sent to the relevant LEA officer who will approve the plant once it is deemed to comply with the various other requirements of EC Regulation No. 853/2004.

3.2 Existing systems

With reference to data gathered during the inspection process and existing Conditions of Approval for the system, identify any non-compliance with the Conditions of Approval or any areas where the system fails to meet purification requirements. Any problems should be identified to the LEA in a letter as soon as possible and within 10 working days of the inspection. A clear distinction must be made between those shortfalls that constitute non-compliance with the Conditions of Approval or purification requirements and recommendations of best practice. This letter must be copied to FSA.

LEAs should be encouraged to give feedback to Cefas regarding any action taken to rectify the identified problems. This could take the form of follow up telephone conversations with the LEA to discuss the problems. If no feedback is received from the LEA within 3 months a further letter should be sent reminding them of the problem and asking what action has been taken. This letter must be copied to the FSA.

If during the inspection it is identified that acceptable changes have been made to the system or the way in which it is operated, it may be necessary to amend the Conditions of Approval document to reflect those changes. In such cases, new Condition of Approval should be

issued with a covering letter to the LEA outlining the changes. In this case a letter and the amended Conditions of Approval must be copied to the FSA.

Amended Conditions of Approval, letters and associated paperwork should be placed on the appropriate file. Ensure that the purification plant database is updated accordingly. Amended electronic versions of Conditions of Approval should be placed in the appropriate site folder.

NB. Conditions of Approval can be amended without an inspection having been carried out. For instance, to accommodate an additional species. In such cases, post depuration end product testing should be requested for the first batch of any new species purified and the steps identified above should also be followed.

3.3 Drawing up a Conditions of Approval Document

**NB. All Conditions of Approval must be forwarded to a trained colleague for double-checking prior to release*.

Following a satisfactory inspection and receipt of acceptable microbiological challenge results (see Part 4), a Conditions of Approval document will need to be drawn up according to the following process:

3.3.1 Conditions

Standard requirements that should be included on all Conditions of Approval documents are given in Table 3. All four identified phrases (Table 3) must be included on the Conditions of Approval document.

Table 3. Phrases to be detailed on all Condition of Approval documents.

1	*All shellfish must be alive and healthy before undergoing purification*
2	*Purification, without disturbance to shellfish, must be for a minimum period of 42 hours once the correct conditions of purification have been achieved.*
3	*UV lamps must be maintained free of slime and other substances, which may impair efficiency of irradiation.*
4	*After each purification cycle the tank must be drained down, without causing re-suspension of sediment, before shellfish are disturbed or removed.*

3.3.2 Specifications

The information entered on the purification centre checklist together with the appropriate manufacturer's details should be used to determine the Conditions of Approval document. Details of the internal measurements of the tank; minimum volume of water; maximum

shellfish capacity and UV system details should be included with the original application and confirmed at the time of inspection using the documented criteria given in Table 4. 5 & 6.

3.3.2.1 *Shellfish loading:*

The shellfish loading arrangements for systems will vary. Table 5 details the maximum capacity and loading arrangements of standard design systems for shellfish species commonly depurated. For those systems of novel design Table 4 should be consulted for guidance on suitable maximum stocking densities. It should be noted that the loading densities stipulated for species such as cockles, clams, and razor clams have further imposed restrictions associated with loading densities. Approval for the maximum stocking density as indicated, would only be granted following additional testing as described in section 4.3.

Table 4. Shellfish permissible loading densities and arrangements**.**

	Loading Density
Pacific Oysters (*Crassostrea gigas)*	530 animals/m^2
Native Oysters (*Ostrea edulis*)	530 animals/m^2
Mussels (*Mytilus spp.*)	50kg/m^2
Cockles (*Cerastoderma edule*) $^{\delta}$	50kg/m^2
Hard clam (*Mercenaria mercenaria*)	70kg/m^2
Native clam (*Tapes decussatus*) $^{\delta}$	50kg/m^2
Manila clam (*Tapes philippinarum*) $^{\delta}$	50kg/m^2
Thick Trough Shell (*Spisula solida*)	50kg/m^2
Peppery Furrow Shell (*Scrobicularia plana*)	50kg/m^2
Razor clams (*Ensis* spp.) $^{\delta}$	50kg/m^2
Sand gaper (*Mya arenaria)* $^{\delta}$	50kg/m^2

* The shellfish capacity for a system can be determined by calculating the surface area of a basket, multiplying by the number of baskets in the system and referring to the density column.

$^{\delta}$ Loading densities subject to species-specific restrictions. See table 3.3.for guidance

Table 5: System capacity & loading arrangements for approved trays for mussels (*Mytilus* species and hybrids*),* Cockles (*Cerastoderma edule*)*,* Pacific oysters (*Crassostrea gigas*), native oyster (*Ostrea edulis*), clams (*Tapes spp.*, hard clam (*Mercenaria mercenaria)* and the razor clam (*Ensis* spp).

Species	Small Scale Std. Des. Allibert 41042 / CPGc1476*		Medium**/**Large Scale Std. Des. Allibert 11031 and Paxton CV4820p* / Allibert 11037**		Vertical stack Std. Des. Modified Allibert 12030	
	Depth	**Max Capacity**	**Depth**	**Max Capacity**	**Depth**	**Max Capacity**
Mussels	80mm	15kg	80 or 100**mm	15kg	-	-
Pacific Oysters	Double Layer	125 oysters 12.5kg	Double Layer	125 oysters 12.5kg	Double Layer	125 oysters 12.5kg
Native Oysters	Single layer Overlapping	125 oysters 12.5kg	Single layer Overlapping	125 oysters 12.5kg	Single layer Overlapping	125 oysters 12.5kg
Clams	80mm	21kg	80mm	21kg	80mm	21kg
Hard Clam	80mm	21kg	80mm	21kg	80mm	21kg
Cockles	80mm	15kg	80 or 100**mm	15kg	80mm	15kg
Razors	Bundles of 12	20kg	Bundles of 12	20kg	Bundles of 10/12	20kg
	Small Scale Std. Des. Allibert 41042 / CPGc1476*		Medium/Large Scale Std. Des. Allibert 11031 and Paxton CV4820p* / Allibert 11037		Vertical stack Std. Des. Modified Allibert 12030	
Species	**Number of trays per stack**	**Number of trays per tank**	**Number of trays per stack**	**Number of trays per tank[2]**	**Number of trays per stack**	**Number of trays per tank**
Mussels	3	6	6/5[1]	48/50[1] (m) 96/100[1](L)	-	-
Pacific Oysters	3	6	6/5[1]	48/50[1] (m) 96/100[1](L)	8	16
Native Oysters	3	6	6/5[1]	48/50[1] (m) 96/100[1](L)	8	16
Clams	2	4	4/3	32/30[1] (m) 64/60[1](L)	6	12
Hard Clam	2	4	4/3	32/30[1] (m) 64/60[1](L)	6	12
Cockles	3	6	1	8/8[1] (m) 16/16[1](L)	3	6
Razors	1	2	1	8/8[1] (m) 16/16[1](L)	1	6
Theoretical maximum possible no.	**3**	**6**	**5/6**[1]	**48/50**[1] (m) **96/100**[1](L)	**8**	**16**

[1] The total number of trays per tank is dependent on tray size. Allibert 11031 trays are slightly shallower and as such it is possible to stack six trays high as opposed to five.

[2] This column displays the total number of trays (m) for Medium Scale Standard Design systems and (L) for Large Scale Standard Design systems.

*Paxton no longer manufacture these trays.

** Allibert 11037 depth of mussels and cockles up to 100mm

For systems based on standard designs and non-standard systems, a trained Cefas officer should determine the appropriate maximum loading stipulation.

Table 6: Optimal stocking densities of the five standard systems for mussels (*M edulis, M galloprovincialis* and hybrids*),* Cockles (*Cerastoderma edule*)*,* Pacific oysters (*Crassostrea gigas*), native oyster (*Ostrea edulis*), Manila clam (*Tapes philippinarum*), native clam (*Tapes decussatus*), hard clam (*Mercenaria mercenaria)* and the razor clam (*Ensis* spp).

System Type	**Mussels** *Mytilus* spp. and hybrids	**Cockles** *Cerastoderma edule.*	**Oysters** Pacific & Native	**Clam** Manila & Native	**Hard Clam** *Mercenaria mercenaria*$^{\delta}$	**Razor Clam** *Ensis* spp
Small Scale 550-600 ltr	90kg	90kg	750	84kg	109kg$^{\delta}$	40kg
Medium Scale 2,000-2,500 ltr	750kg	120kg	4,150	500kg	650kg$^{\delta}$	145kg
Large Scale 4,000-4,500 ltr	1500kg	240kg	12,000	1000kg	1300kg$^{\delta}$	290kg
Bulk Bin 1,100 ltr Bin	300kg	-	-	-	-	-
Vertical Stack 650 ltr sump total 16 trays	-*	80kg	2000	224kg	288kg$^{\delta}$	105kg

δ Due to the density of shell, hard clams can be stocked to a level 1.3 x that of Manila and native clams

* Due to the movement of mussels climbing out of these systems trays it is generally recommended that the vertical stack system is not used for purifying mussels. However, if used, any mussels found to be out of the water during the 42 hour cycle should be discarded.

The depth of water above the depurating shellfish must also be stipulated. For mussels, trays must be arranged in such a way as to ensure a minimum water depth of 80mm above each layer at the beginning of the cycle. For all other species it is 30mm. This stipulation should be included in the Conditions of Approval document.

3.3.2.2 Flow rate:

The flow-rate* specified for systems will vary according to a number of factors such as the type of system, the detailed plumbing arrangements, the shellfish to water ratio and the type of shellfish being depurated e.g. species such as mussels have a high metabolic requirement for oxygen and therefore a higher flow rate may be required. Most new systems will be based on standard Seafish designs and therefore the flow rates specified in Table 7 should be stated as minima unless observed at a higher rate at the time of approval pending a successful microbiological challenge.

Table 7: Minimum flow rates stipulated for Approval for standard design systems.

System Type	Small Scale 550-600 litres	Medium Scale 2,000-2,500 litres	Large Scale 9000 litres	Bulk Bin 650 litres Bin	Vertical Stack 650 litres sump
Minimum Flow Rate	20 L/min 1.2m^3/hr	208.3 L/min 12.5 m^3/hr	158.3 L/min 9.5 m^3/hr	108.3 L/min 6.5m^3/hr	15 L/min 0.9m^3/hr

This should be similar to the flow rate noted at the time of inspection. If the flow rate during the time of challenge is in excess of this minimum, then the specific rate recorded at the time of inspection will be stipulated as the minima in the Conditions of Approval document.

NB All new systems must be fitted with a flow meter.*

3.3.2.3 UV lamps:

- Number and wattage of UV lamps
  The UV specification installed must meet the minimum applied UV dose requirement of not less than 10mJ/cm^2 (100J/m^2)*. The UV units will vary according to a number of factors such as the number and wattage of lamps per unit, the detailed plumbing arrangements (i.e. parallel or flow through) and the volume of the activation chamber. These details should be entered into the UV spreadsheet to ensure the minimum UV dose is met.

  * West's (1986) recommendation of using an applied dose (fluence) of not less than 10mJ/cm^2 (100J/m^2), with the associated text "one 30 watt lamp unit is sufficient to continuously treat 2200 litres of seawater in a re-circulation system" is used as the basis for the current approach to depuration system approval in terms of minimum applied UV dose in England and Wales. Design changes over the last three decades have led to an increase in stocking densities of shellfish within systems. This has resulted in the need to increase flow rates to provide sufficient dissolved oxygen to the depurating molluscs. This in turn has required an increase in the UV disinfection specifications for these systems.

- UV lamps operating hours specification.
  In the absence of the manufacturer's specification details for a particular lamp, a default period of 2,500 hours use should be set (Table 8, 2a). If however, the applicant can provide such details, then the longer period as specified by the manufacturer may be used (Table 8, 2b). The longevity of use for a given bulb is set by the number of consecutive hours of use, for which the bulb is defined by the manufacturer as operating at >80% efficacy.

Table 8: Standard phrases to be used within the Conditions of Approval concerning UV sterilisation.

1	*The system must be fitted with a [2x 25 Watt][1] or greater, UV lamp.*
2a	*UV lamps must be changed after every 2,500 hours of use. A record of UV usage must be kept for this purpose.*
2b	*The [TMC GE25W][2] lamps use in association with this system must be changed after every [4000][3] hours of use. All other types of UV lamp must be changed after 2,500 hours of use. A record of UV usage must be kept for this purpose.*

[1] Insert UV specifications.
[2] State appropriate make and model.
[3] State appropriate number of hours operation at >80% efficacy

Phrase 1 as identified in Table 8 is a generic phrase that must be included in all conditions of approval. The use of either phrase 2a or 2b within the conditions of approval will be based on the available information at the time of inspection.

3.3.3 Seawater

Minimum temperatures and salinities should be stated for all species of shellfish to be included on the Conditions of Approval. The current requirements are given in Table 1.

3.3.3.1 Seawater re-use

The re-use of natural seawater is permitted for certain species and types of system, provided that there is adequate provision for storage of the water drained from the system at the end of the cycle. The remaining water in the tank that is below the shellfish must be discarded, as this will contain the shellfish faecal material egested during the cycle. The main reasons for limiting the re-use of seawater are:

- The possible build-up of shellfish metabolic by-products e.g. ammonia leading to inhibition of shellfish activity.
- The possible build-up of contaminants from batch to batch.

In the absence of an adequate storage vessel, reuse of seawater is not permitted and the Conditions of Approval must reflect this.

The re-use of natural seawater is normally limited to 2 weeks with an allowance for an extra 2 weeks should exceptional weather conditions prevent the collection of water of suitable quality for small-scale systems (Table 9: 1a). Records must be kept for such extended use.

Where permitted artificial seawater may be used for 4 weeks providing at least 10% is replaced after each cycle and that the shellfish to water ratio is not excessive (Table 9: 1b). For the high-density systems where the shellfish to water ratio is relatively low, such as the medium scale system and some bulk bin systems (1:3 compared with 1:6 for small scale shallow tank), re-use is limited to 3 purification cycles for both artificial and natural seawater (Table 9: 1c, 1d and 2).

For the depuration of cockles and razor clams (and the depuration of any mussels in bulk-bin systems with less than 3:1 ratio) the reuse of seawater is not permitted. As a consequence either phrase 2 or 3 as identified in Table 9 should be included in the Conditions of Approval document.

Table 9: Standard phrases to be used within the Conditions of Approval concerning the reuse of artificial and natural seawater.

1a	*Natural seawater should not normally be re-used for more than 2 consecutive weeks. However, extended re-use up to a maximum of one month is permitted where exceptional climatic or other circumstances dictate. A record must be kept when seawater is used for such extended periods.*
1b	*Artificial seawater may be used for a maximum of 15 cycles or up to one month, provided that 10% is replaced each time.*
1c	*Natural seawater should not be re-used for more than 3 purification cycles.*
1d	*Artificial seawater should not be re-used for more than 3 purification cycles.*
2	*For 'Bulk Bin' systems, seawater should not be re-used for more than 3 purification cycles. Reuse is only permitted where separate storage facilities are available to enable thorough cleaning of the sump between cycles.*
3	*For sand gapers, cockles and razor clams the reuse of seawater is not permitted.*

3.3.3.2 Sea water pre treatment (Clarification and Sterilisation)

All seawater must be sterilised by UV irradiation (or ozone see 3.3.3.3) prior to depuration. This is normally achieved by filling the system through the operational UV steriliser (Table 10:1a). Alternatively seawater may enter the system directly. Given this scenario the water within the system must be recirculated through the operational UV unit for a minimum of 12 hours prior to depuration (Table 10:1b).

3.3.3.3 The use of Ozone in purification plants

Ozonation may be used in depuration systems providing ozone does not come into direct contact with the shellfish and does not create harmful by-products that may affect the safety of the shellfish (2010 FSA). Residual ozone must be removed from seawater before it comes in contact with the shellfish such that the ORP of seawater entering the tank containing shellfish must be within 10% of the base line ORP of the untreated seawater.

Table 10: Standard phrases to be used within the Conditions of Approval concerning seawater pre-treatment, clarification, UV and Ozone treatment

1a	*Seawater entering the system directly must be re-circulated through the UV unit for 12 hours prior to use*
1b	*Seawater must enter the system via the operating UV steriliser*
1c	*For 'Bulk Bin' systems, all recirculating seawater must pass through the operational UV steriliser prior to entering the bin(s) containing bivalve molluscs.*

2	*The Natural Seawater to be used in this system is required to be clarified by settlement for a minimum period of [12 hours][2] prior to us. Clarified water must be UV treated prior to depuration*
3	*The natural seawater to be used in this system is required to be clarified before use with an 'in-line' [TMC Hydro Clean Cartridge filter][1] This should be used in accordance with the manufacturers instructions and cleaned on a regular basis.*
	The maximum continuous ozone dose that shall be applied should not exceed 320mV oxidative redox potential (ORP). Residual ozone must be removed from seawater before it comes in contact with the shellfish such that the ORP of seawater entering the tank containing shellfish must be within 10% of the base line ORP of the untreated seawater

[1]State appropriate filter type and manufacturer.
[2]State appropriate time in hours.

For systems employing natural seawater for the purpose of depuration turbidity or clarity may be an issue. Turbidity is considered to be a limiting facto in ultraviolet disinfection due to organic suspended particles absorbing ultraviolet light irradiation and consequently reducing the efficacy of the process. In order to ensure that UV treatment is effective prior to and during depuration, it is essential to ensure that fine particulates are removed. Where moderate to gross turbidity problems occur, natural seawater will require settlement prior to its use for a minimum period of 12h assuming 1:1 mixing and flow rate of one full exchange per hour. In these cases phrase 2 from Table 10 should be included in the Conditions of Approval document.

The settlement tank must be of sufficient volume, fitted with a sump drain for removal settled particulates and a separate outlet for water to be used for depuration. This outlet should be situated at least 100mm off the floor of chamber and orientated in such a way that the sediment is not disturbed during drain down procedures.

For some sites the use/installation of settlement tanks may not be appropriate due to constraints placed on the operator in terms of space. An alternative approach for the removal of fine particulates (reduction of turbidity) is the installation of 'in-line' cartridge or sand filter. Approval must be dealt with on a case-by-case basis. A copy of the manufacturer's specification and application of the unit must be provided to Cefas and placed on file together with any comments made the trained Cefas officer. In such cases, Phrase 3 as detailed in Table 10 must be included in the Conditions of Approval document.
Cefas and Seafish guidance on depuration system water quality:
https://www.cefas.co.uk/media/52850/2012-water-quality-in-purification-leaflet.pdf

3.4 Covering letter

A covering letter should accompany the Conditions of Approval document, which must be sent to the LEA officer who has responsibility for approving the purification plant. Below is a standard form of words that should be included in this letter. Any unusual or outstanding items that need to be addressed should also be included in this covering letter.

"*Please find enclosed the Conditions of Approval document for the shellfish purification system "**X**" operated by "**name of company**". These are written for compliance with the Regulation (EU) No. 853/2004 of the European Parliament and of the Council and form part of the documentation required for approval of purification systems under these regulations.*

These Conditions of Approval should be attached to your approval document for issue to the operator and should be readily available and displayed within the establishment. The documents should be read in conjunction with the Regulation (EU) No. 853/2004 of the European Parliament and of the Council and in particular Sec VII, Chap.IV -Requirements for purification centres part 2.

Any technical modifications to the system should be notified to us by yourselves so that the possible implications of such changes can be assessed."

Any other specific requirements should also be mentioned in the covering letter and should be copied to the FSA. Ensure that all inspection checklists, associated information, letters and Conditions of Approval documents are placed on the relevant electronic and paper file and that the database is updated.

3.5 Post visit letter

During each inspection particular attention should have been given to ensuring both the operator and the LEA officer were aware of any problems. Further effort should have made to ensure that both were aware of any detrimental effect on the depuration process that may be caused as a result of the problem.

LEA officers should be sent a letter outlining the findings from the inspection and emphasising the significance of any problems found together with any amended conditions of approval.

Further follow up letters should be sent to LEA officers 3 months following initial notification asking for assurances that action has been taken to correct these problems. Cefas, if required, will make further inspections.

If no satisfactory response is received from the LEA, a letter should be sent to the FSA and copied to the LEA highlighting the current situation.

4 Microbiological Challenge

4.1 Microbiological Testing of purification systems

For new premises, on receipt of the of the 'Depuration request to inspect' Data Sheet (Form D004), it should be apparent what type of system (standard or non- standard design etc.) is requiring validation. This will normally fall into one of three categories: Standard Design systems, systems based on Standard Design system technology i.e. those systems identical in form and function but differing in their capacity or some other aspect and Non-Standard Design systems.

For existing premises two possible scenarios exist. Systems requiring approval may be identical to existing systems already approved on site or they may be of a novel design for the site in question.

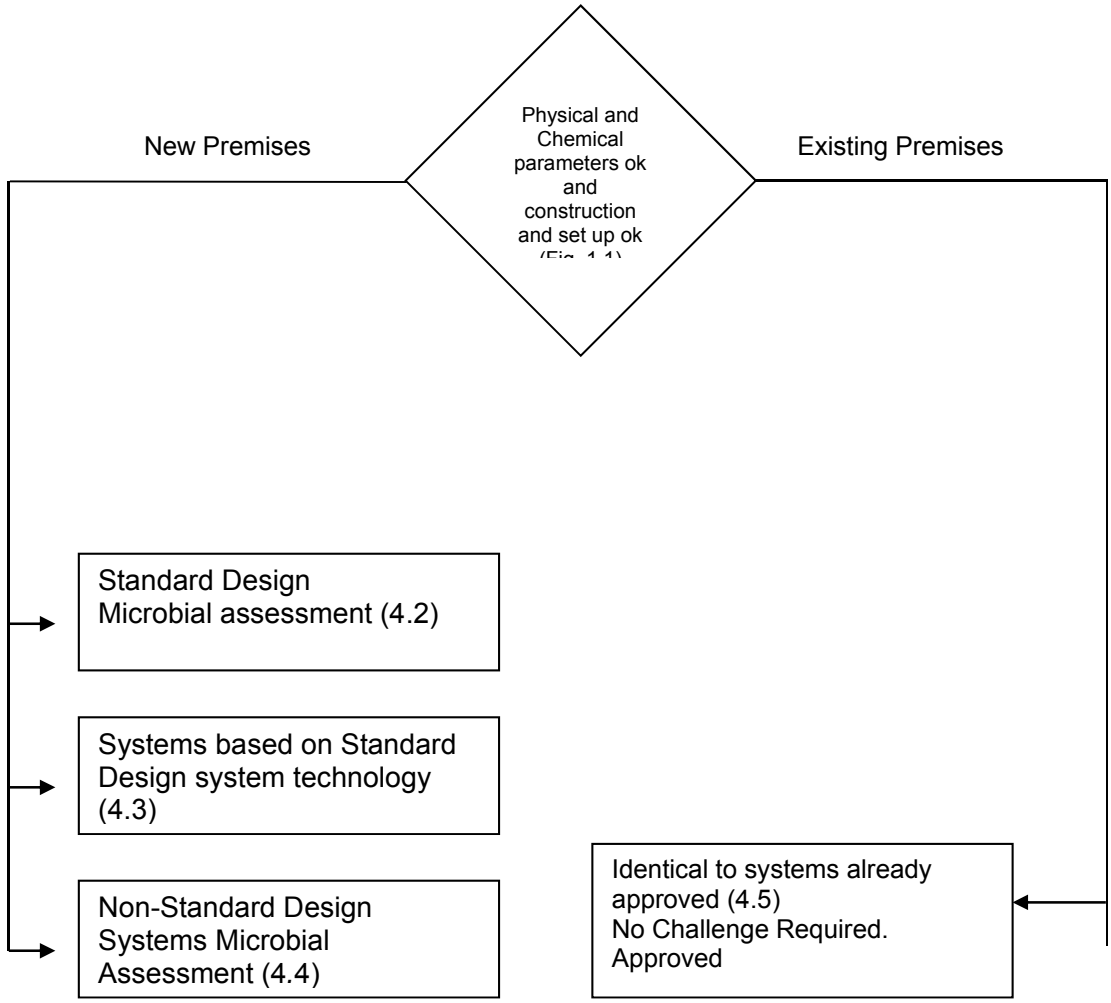


Figure 2: Microbiological testing scenario schematic.

Microbiological testing of purification systems is just **one** aspect of the procedures used to assess the suitability of a purification system for approval. Before conditions of approval can

be written for a new purification system, it must be demonstrated among other things, that the system in question is capable of achieving an acceptable reduction of *E. coli* levels in shellfish during depuration i.e. that end-product standards are met (<230/100g). However, a properly functioning system should be able to reduce *E. coli* levels from ≤ 4,600 *E. coli* / 100g, to less than 80 *E. coli*/100g in 42 hours.

- All new systems:

  If more than one system of the same type is being commissioned at the same time it is only necessary to test one system unless there are reasons to suspect there may be problems or if systems differ in design.

- Modified systems may require further microbiological testing if the modification is thought likely to have a significant effect on the effectiveness of purification -this will be based on the judgement of a trained Cefas officer.

In all cases Food Authorities are responsible for ensuring that all results are forwarded to Cefas for evaluation prior to the issuing of Conditions of Approval.

For the purposes of the Approval process, the enumeration of *E.coli*/100g of shellfish flesh should be conducted using ISO TS 16649-3 by laboratories specifically accredited for this method. All testing laboratories should be specified official control laboratories for the provision of Official Control services for shellfish as required by Regulations (EC) 854/2004 For monitoring of *Escherichia coli* in shellfish.

4.2 New premises: Standard Design System(s).

To provide the system with a reasonable test, shellfish containing an *E. coli* loading of at least 2000/100g should be used. They should preferably be from a class B site. If, however, the local class B shellfish are not sufficiently contaminated a number of options are available:

4.2.1 Use a full load of class C shellfish

In this situation it is up to the LEA officer to ensure that the shellfish do not go for human consumption, but are relayed for at least 2 months in a designated class A/B relay area or are replaced in the class C area.

4.2.2 Part load with class C shellfish for sampling only

The class C shellfish should be clearly marked (preferably in sealed net bags) and used for sampling purposes. The rest of the load may be class B (or class A) but at the end of the cycle, all of the shellfish must be placed back in the harvesting area or in a designated class A/B relay area for at least 2 months.

4.2.3 Artificially contaminated shellfish

Shellfish contaminated with artificially prepared cultures of *E. coli* do not provide an adequate test of depuration efficacy, as the bacteria are more easily removed by the depuration process. The only realistic way of artificially contaminating shellfish is with sewage e.g. by placing shellfish near an outfall or bioaccumulation using primary effluent. Shellfish contaminated in this way will have unknown virus levels and must be assumed to be of prohibited status. As such, at the end of the cycle, the shellfish must be placed back in the harvesting area for 6 months before they can be harvested for human consumption.

The LEA officer must be made aware that he/she is responsible for ensuring that the appropriate controls are placed on such shellfish.

The system should then be loaded to its full-intended capacity (approval may only be given to operate at the capacity inspected except for standard designs) and the purification cycle started. The inspection visit is normally timed so as to coincide with this test purification cycle. A full assessment of the operation of the system will be conducted in the presence of both operator and LEA officer. During this visit a visual assessment of the systems suitability to task should be made and findings documented accordingly:

- Salinity
- Temperature
- DO_2
- Turbidity
- Flow rates
- Activity
- Loading density and species

At the end of the cycle, at least 3 samples should be taken for *E. coli* testing. These should be taken from what might be the most, medium and least effective areas of the system e.g. cascade, middle of system and suction bar.

4.2.4 Results

Results from a bacterial test are generally considered to be successful if the levels post depuration are found to be below the end-product standard levels of 230 *E. coli* /100g of shellfish. However if initial levels of *E. coli* were below 4600 /100g, then post-depuration levels would be expected to be at or below 80 *E. coli* /100g. Failure to achieve clearance to this level may indicate a problem with the purification system. Under such circumstances a retest of the system may be requested despite achieving the end-product standard. Alternatively, increased testing of the end-product may be required to ensure compliance with the standard for several depuration cycles.

NB effective depuration systems should regularly yield results of ≤80 E. coli per 100g.*

4.2.4.1 Pre-depuration E. coli/100g <2000

If on the receipt of the microbiological results it is established that pre-depuration shellfish contained significantly less than 2000 *E. coli*/100g, it will normally be necessary to repeat the

challenge analysis with shellfish from a more contaminated source in order to successfully demonstrate the efficacy of the system. If a repeat test is considered by the Cefas officer to be unnecessary e.g. if a result of 1700 was obtained and the operator is experienced and/or considered competent then a higher than normal frequency of initial post depuration end product testing (e.g. first 3 batches) may be requested to confirm ongoing compliance.

4.2.4.2 Post-depuration E. coli/100g >230 E.coli/100g:

Shellfish must comply with end-product standard levels of 230 *E. coli* /100g of shellfish. There are two distinct situations that may arise. For systems containing shellfish initially contaminated at a level of between 2000 – 4,600 *E. coli* /100g (class B), a revaluation of the system will be required in order to identify potential reasons for the failing prior to any re-test. For systems containing shellfish initially contaminated at a level of > 4,600 *E. coli* /100g (class C) a re-test using shellfish from a less contaminated source will be required to demonstrate the systems capability in conforming to the end-product standard.

If the results are <230 but >than 80 *E. coli* / 100g the LEA should be requested to initially increase the frequency of end-product testing. Cefas would normally request that the first three batches of shellfish are assessed both pre and post depuration. In the event that the efficacy of depuration is still questionable i.e. <230 but > 80 *E. coli* / 100g, a trained Cefas officer should contact the relevant LEA officer with recommendation of a re-visit.

4.3 New premises: New systems based on standard design system technology.

An initial visit may be required to evaluate the system before a final decision on proceeding with the microbiological challenge is made (4.4.1).

The operator may be required to fully load the system for demonstration purposes. During this visit a visual assessment of the systems suitability to task should be made. The inspection should be treated as a routine inspection and findings documented accordingly.

- Shellfish to water ratios as stipulated for standard design systems will be adopted in the formulation of the Conditions of Approval document.

If a maximum load has been stipulated for a particular species as a precautionary basis (i.e. less than that generally applied for a type of system), then this may be reviewed at the request of an operator. In these cases the microbiological assessment as detailed for non-standard design systems will be required.

NB Conditions of Approval will not be issued until a full and satisfactory microbiological challenge has been obtained*

To provide the system with a reasonable test, shellfish containing an *E. coli* loading of at least 2000/100g should be used. They should preferably be from a class B site. If, however, the local class B shellfish are not sufficiently contaminated then the options under 4.2 should be explored.

4.4 New premises: Non-standard design systems

For novel systems, which are distinctly removed in terms of design from standard design systems, a different approach is warranted. On receipt of the 'Request to Inspect' data sheet a preliminary assessment based on this information, as to whether an approval visit is at all worthwhile must be conducted e.g. systems that introduce water from jets or spray bars situated on the floor of the tank would be deemed inappropriate as the system would not allow sedimentation directly impacting on depuration efficacy: the use of mechanical and biological filters. It may be that a report of an appropriate technical evaluation is available, including those aspects identified in section 4.4.2.2 below. If this is the case, the Cefas officer should undertake an assessment of the report, taking into account any available information on the competence of the organisation or individual that has produced it.

Such systems may require a pre-inspection visit at an early stage in the presence of both operator and LEA officer to assess overall suitability for depuration.

4.4.1 Preliminary visit

An experienced Cefas officer is responsible for deciding if the system requires a preliminary visit. In some instances it may well be apparent from the documentation supplied that the system in question is simply not suited to task. An initial visit should be undertaken for all non-standard design systems where the supporting paperwork leaves doubt as to the suitability or operation of the system. A preliminary visit may also be deemed appropriate for standard design systems under certain circumstances. This should be conducted in the presence of both operator and LEA officer (Inspection and Re-inspection SOP).

Any pre-visit undertaken should be made at the earliest possible opportunity e.g. during the construction process and is designed to identify any potential design issues with reference to the suitability of the system and whether its design or proposed operation would fail to meet purification requirements. During the visit clarification should be sought on the species, shellfish to water ratios, proposed stocking densities, loading arrangements, UV treatment, flow rates, flow dynamics etc, as detailed in part 2 of this document.

An experienced Cefas officer will then be responsible for deciding if the system is suitable for purpose of depuration. An inspection made at this time is aimed to assist industry, informing operators of potential problems or design features that would not meet the criteria for depuration on formal inspection prior to the completion of the build.

4.4.2 Microbiological assessment of novel system

In the absence of experimental evidence obtained by Cefas or Seafish to support depuration efficacy for novel systems for a given species at pre-described stocking densities, a thorough evaluation of the systems capability must be investigated. Investigations into the efficacy of systems will normally be conducted using the 'Benchmark Species' namely mussels (*Mytilus* spp.) due to their high metabolic rates. However, if mussels are not intended to be depurated,

alternative species for system assessment have been identified in Table 11 and ranked preferentially. Following the receipt of a successful series of challenges (4.4.2.1) and knowing the loading density of the 'Benchmark Species', the stocking densities for any additional species required can be prescribed based on established shellfish to water ratios as stipulated for standard design systems.

Table 11: Preferentially ranked species for the evaluation of novel systems.

1	Mussels
2	Pacific oysters
3	Native oysters
4	Cockles
5	Hard shell clams (*Mercenaria mercenaria*)
6	Clams (*Tapes* spp.)

4.4.2.1 System evaluation testing

This investigation will focus on the depuration of a full load of the 'benchmark species'. The assessment will be conducted at the minimum, median and maximum temperature described for the species and undertaken at the site (Table 12).

Table 12. Species maximum and minimum temperatures for depuration**.**

	Minimum Temperature (°C) *	Maximum Temperature (°C) $^{\delta}$
Pacific Oysters (*Crassostrea gigas)*	8	18
Native Oysters (*Ostrea edulis*)	5	15
Mussels (*Mytilus edulis*)	5	15
Cockles (*Cerastoderma edule*)	7	16
Hard clam (*Mercenaria mercenaria*)	12	20
Native clam (*Tapes decussatus*)	12	20
Manila clam (*Tapes philippinarum*)	12	20
Razor clams (*Ensis spp.*)	10	-
Sand gaper (*Mya arenaria*)	10	-

* Cefas criteria for approval of depuration systems.
$^{\delta}$Seafish recommended (Seafish Operating manuals).

For systems subject to seasonal temperature change there are three key stages requiring efficacy testing, unlike temperature-controlled systems* requiring only one. Each key stage (Figure 3) must demonstrate clearance to end-product standards. Each stage will be assessed in duplicate and will ordinarily consist of the following:

- For systems of 650L or less, 3 pre-depuration samples and three post depuration samples. A total of 12 samples.

- For systems of 600L to 2500L, 3 pre-depuration samples and 6 post depuration samples will be required. A total of 18 samples.

NB A trained Cefas officer may request additional testing for complex or stacking based systems.*

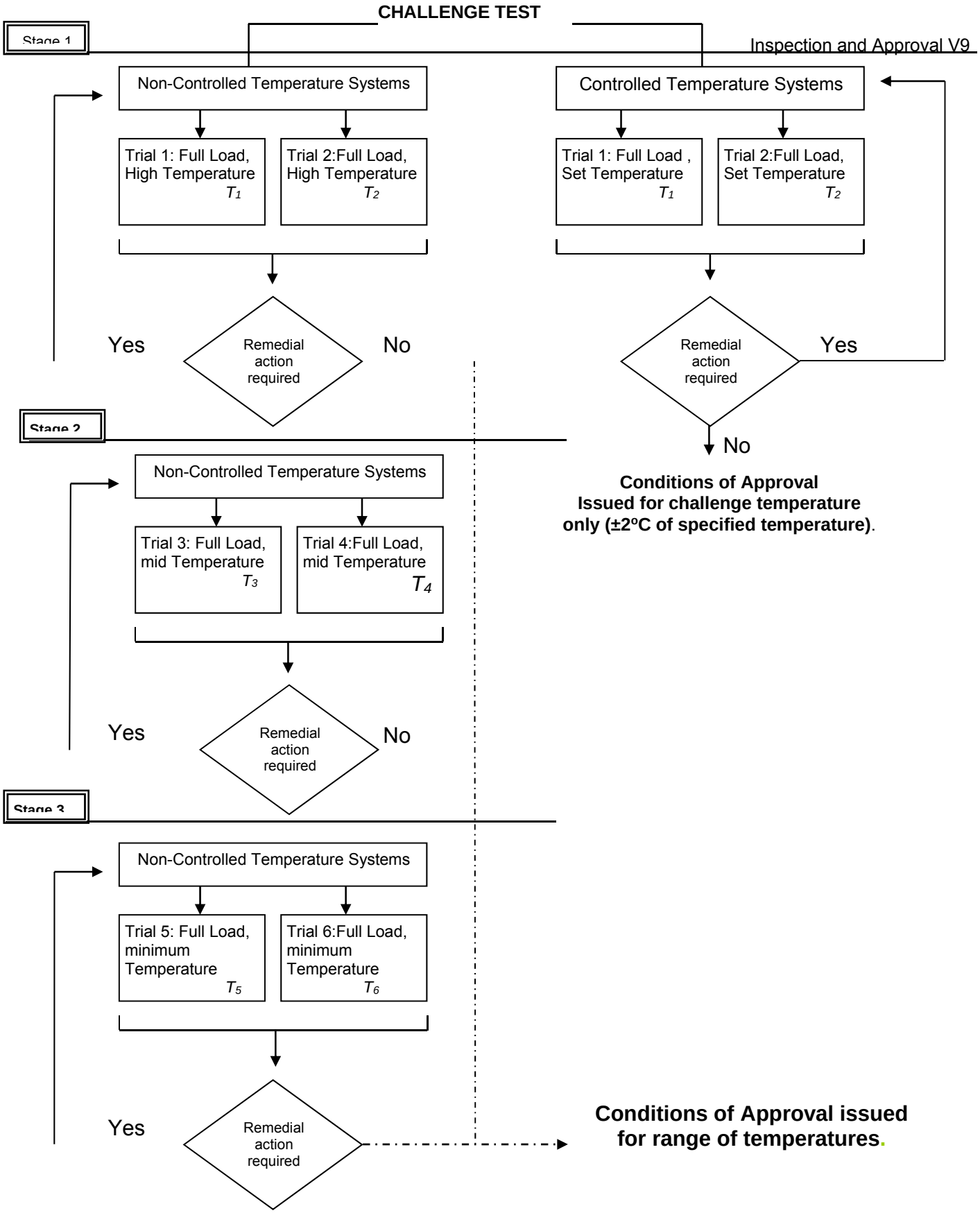


Figure 3. Flow diagram depicting the sequential events and stages during Novel System validation.

4.4.2.2 Intra-challenge assessment:

The LEA officer will be responsible for ensuring that the following assessments are made for each trial and details correctly recorded throughout the depuration cycle:

- Date and time at the start and end of cycle
- Flow rate
- UV lamp operation
- Water temperature
- Water salinity
- Water clarity
- Dissolved oxygen levels – water entry and exit points
- Mollusc activity
- Stocking density
- Results pre and post depuration as required

A trained Cefas officer will be present to assist the LEA officer and operator during the first depuration trial. The Cefas officer will preferably be in attendance to evaluate the drain down procedures.

All subsequent trials will be undertaken by the LEA officer who will be responsible for depuration assessments and all provision of appropriate records as previously stated (record templates available from Cefas on request).

To provide the system with a reasonable test, shellfish containing an *E. coli* loading of at least 2000/100g should be used. They should preferably be from a class B site. If, however, the local class B shellfish are not sufficiently contaminated a number of options are available (4.2).

4.4.3 Challenge Test Results

Results from a bacterial test are generally considered to be successful if the levels post depuration are found to be below the end-product standard levels of 230 *E. coli* /100g of shellfish. However if initial levels of *E. coli* were below 4600 /100g levels should routinely be cleared to ≤80 *E. coli* / 100g. Failure to achieve this level of clearance may indicate a problem with the purification system. Under such circumstances a retest of the system may be requested despite achieving the end-product standard.

On the receipt of the 'stage' results, the LEA officer will make an assessment of the data and will either request a repeat of the stage evaluation (due to individual trial failures) or continue with the system evaluation. Following the completion of each stage the LEA officer. Cefas will be able to provide advice to the LEA officer with regard to evaluation.

Two consecutive passes are required for completion of each stage (i.e. replicate samples for paired trials (e.g.T1 and T2) are required to demonstrate clearance to end-product standards). Stage failures require remedial action if appropriate and successful re-testing before advancing to the next stage of analysis. Remedial action will normally involve either increasing flow rates subject to restrictions imposed by the UV sterilisation system employed

or reduction in stocking density. Specific advice on this should be sought from Seafish or other suitable consultants.

Persistent failures will result in the termination of the efficacy testing programme and approval process for the system in question. No Conditions of Approval will be issued given this scenario.

Successful completions of all stages as mapped in Figure 3 are required prior to approval. On completion all four stages the LEA will forward the appropriate information to Cefas for final evaluation prior to the issuing of Conditions of Approval.

5 Associated Literature and References

Legislation

1. Regulation (EU) No. 853/2004 of the European Parliament and of the Council.

Industry guidance to purification and related issues

2. Sea Fish Industry Authority
   Guidelines for the Facilities and Equipment Required for Handling Bivalve Molluscs from Harvesting through to Distribution to Retail Outlets-Final draft. February 1997.

Standard system verification

3. SEAFISH Generalised Operating Manual for Purification Systems of Non-Standard Design.March 1995.
4. SEAFISH Operating Manual for the Small Scale Shallow Tank Purification System.March 1995.
5. SEAFISH Operating Manual for the Medium Scale Multi-layer Purification System.March 1995.
6. SEAFISH Operating Manual for the Large Scale multi-layer Tank Purification System.March 1995.
7. SEAFISH Operating Manual for the Bulk Bin System for Mussels. March 1995.
8. SEAFISH Operating Manual for the Vertical Stack System. March 1995.
9. Shellfish Association of Great Britain Guidance on the Frequency of Microbiological Sampling of Purified Molluscs by Operators of Purification Centres. February 1995.
10. Cefas Determination of Appropriate Conditions for the Depuration of Razor Clams October 1999.

HACCP

11. MAFF / DFR Shellfish Hazard Analysis Critical Control Point (HACCP) Concept: Application to Bivalve Shellfish Purification Systems.
12. P.A.West 1986. Hazard analysis critical control point (HACCP) concept; application to bivalve shellfish purification systems. Journal of the Royal Society of Health 4:133-140.

UV disinfection/Ozone

13. Bark, S.J. 2005 Internal report. UV Disinfection in Depuration Theory and Practice
14. Bolton, J, R. 2001. Ultra violet applications handbook, second addition. Bolton photosciences incorporated.
15. Boulter & Wilson. 1998. Ultraviolet Light Sterilisation of Seawater with reference to Shellfish Depuration Tanks. Seafish Report, No. SR520
16. Hoyer, O. 1998. Testing performance of UV systems for drinking water disinfection. Water supply, Vol. 16, Nos 1/2, 419-442.
17. Kelly C B. Disinfection of Seawater by Ultraviolet Radiation. Am J. Pub. Health.Vol 51 p 1670 – 1680.

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19. Personal communication: Dr Andy Albrecht. (GE Consumer and Industrial). (Details on internal file FDR 3797)
20. Personal Communication: Mr Nick Bridle (TMC Bristol). (Details on internal file FDR 3797)
21. P.A.West 1986. Hazard analysis critical control point (HACCP) concept; application to bivalve shellfish purification systems. Journal of the Royal Society of Health 4:133-140.
22. Cefas 2010 https://www.cefas.co.uk/media/52849/20100827-ozone-discussion-document-uk-final.pdf
23. FSA 2010 USE OF OZONE IN SHELLFISH DEPURATION PLANTS https://www.food.gov.uk/sites/default/files/multimedia/pdfs/enforcement/enfe10035.pdf

Cefas SOP's

SOP 1281 Training
SOP 1282 Pre-Inspection
SOP 1283 Inspection and Re-inspection
SOP 1285 Measurement and Calibration
SOP 1286 Post Inspection
SOP 1287 Risk Assessment Based Selection for Annual Re-inspection Programme
SOP 1673 Depuration inspection Purchasing and supplies
D024 Inspection and Approval of Purification Plants Guidance Notes for Local Enforcement Authorities.
SOP 2211 Depuration Plant Inspection Service Biosecurity Measures