guardians of drinking water quality
DRINKING WATER INSPECTORATE

Review of the Adequacy of Existing Proposals for Membrane Integrity Monitoring

Final Report[1]- Commercial in Confidence

Client: Drinking Water Inspectorate

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Approved: C.Jackson - Deputy Chief Inspector

Signed:

Date:

1. This report and its conclusions, recommendations and suggestions are based on the assessment of a small selection of documents and information. Its conclusions are those of the authors. Any statements of satisfaction represent the Assessors' opinions at the time, based on the information available to them, and do not constitute a general endorsement of the adequacy of any Company's procedures or practices

CONSEPT
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INDEX

1 EXECUTIVE SUMMARY

1.1 Background

Regulation 23B of the Water Supply (Water Quality) (Amendment) Regulations 1999[1] sets a treatment standard for water treatment works deemed to be at significant risk from *Cryptosporidium* oocysts. Water companies are permitted to install appropriate treatment, as an alternative to continuous sampling and monitoring, provided it meets the performance specifications given in guidance issued by the Drinking Water Inspectorate (DWI), i.e. continuous removal of particles greater than 1µm diameter.

Appropriate membrane filtration will meet these specifications but there will need to be an adequate level of monitoring in order to demonstrate that all the required criteria are fully met. As part of the regulatory system, water companies installing membrane filtration are required to provide proposals to the DWI detailing the associated level of integrity monitoring.

If a membrane system is installed, there should ideally be a continuous monitoring of filtrate quality to ascertain that the membrane is functioning effectively. However, there are no on-line monitors for *Cryptosporidium* (other than those used for continuous sampling) and current water quality monitors for surrogates are not considered robust, reliable or sensitive enough. Membrane integrity test procedures are attractive since they can be performed in routine operation and can be automated. However, established routine membrane integrity tests (MITs) are usually undertaken off-line with the type of test selected depending on the membrane manufacturer and membrane system supplier. At present, with current routine technologies, continuous on-line membrane integrity monitoring is not a practical option, although new technologies using acoustic sensors or on-line challenge tests may present future options

1.2 Objectives

DWI engaged Consept to advise on the assessment of low-pressure membrane integrity monitoring. A programme of work was established with the following four objectives.

1. To define the criteria against which water company or suppliers' proposals for checking the integrity of drinking water treatment membranes would be evaluated.
2. To evaluate water company and suppliers' proposals for installation and operation of membranes and to advise on whether they meet with the defined criteria.
3. Where proposals are inadequate, to make recommendations for improvement.
4. To draft generic solutions based on the results of initial assessments so that a standardised approach can be produced for each type of membrane.

1 Now Regulation 29 of the Water Supply (Water Quality) Regulations 2000

1.3 Methodology

Information on membrane integrity testing (MIT) was collected from the membrane companies approved for *Cryptosporidium* removal; detail of membrane plant procedures was obtained from water companies. This material has been reviewed and assessed to determine if planned or current MIT can be adequately undertaken in a water company routine operational environment.

1.4 Conclusions and Recommendations

The project team makes the following conclusions and recommendations with referenced sections of the report in brackets.

1.4.1 Objective 1

To define the criteria against which water company or suppliers' proposals for checking the integrity of drinking water treatment membranes would be evaluated.

- The criteria required in a MIT proposal has been identified and listed in Table 6.2 of this report. [6.2]
- DWI should produce a detailed guidance note for water companies to assist development of MIT proposals. See Table 6.2 and, in particular, section 5 thereof.
- DWI should publish specific principles and update the guidance note. See Table 8.2.
- Water companies must have had their specific site MIT proposals agreed by the DWI before they can cease compliance monitoring at that site. [6.2, 7.3]
- DWI should clarify those aspects of CPP approval where it covers membrane elements or membrane systems.
- DWI should clarify the criteria employed by the LGC to determine the 1ìm absolute removal so that a consistent approach is taken (see Appendix H).
- There are different interpretations of the 'compliance dates'. [7.3]

1.4.2 Objective 2

To evaluate water company and suppliers' proposals for installation and operation of membranes and to advise on whether they meet with the defined criteria.

- No existing proposals have yet been identified that adequately routinely monitor membrane integrity on water companies' operational sites. [7.1]
- Water companies differ in their interpretation of the DWI requirement. A well-defined guidance note is needed to ensure that companies produce adequate and consistent information that can then be used to benchmark comparisons. [8.1.11]
- Some water companies have assumed that CPP approval for membranes indicates that the MIT has been approved under 'instructions for use'. [7.3, 8.1.2]
- Membrane elements, membrane system configurations and MIT procedures differ. At this stage it is not possible to produce generic guidelines. [4.4, 5.7]
- Responsibility to produce acceptable proposals rests finally with the water companies. Companies installing membrane systems will need to ask the manufacturers/ suppliers to provide full details of their system of monitoring the

integrity of the filtration system and adapt them to meet operational requirements. [5.7, 8.1.3]

- The water companies will also need to assess whether these procedures are adequate for the system design and, if so, integrate them into site specific procedures at each treatment works. [8.1.3, 8.1.10]
- The DWI guideline requiring continuous process (membrane integrity test) monitoring of an "absolute 1µm barrier" is not feasible with current technology. [8.1.1, 8.1.7, 8.1.13, 8.1.14]
- From the limited number of audits performed, it is anticipated that once plants have been transferred from commissioning to operations, the water companies will be able to refine MIT proposals encompassing most of the criteria listed in Table 6.2. However, DWI should give the water companies guidance before they can issue a complete MIT proposal; see Table 8.2. The proposals can then be fully validated and tested. [6.2, 7.4, 8.2]

1.4.3 Objective 3

Where proposals are inadequate, to make recommendations for improvement.

- The Proposals should address all the criteria in Table 6.2 and, in particular, section 5 thereof. [6.2]
- Hollow fibre membrane integrity procedures are well developed but need to be adapted and incorporated into company specific proposals. There is a paucity of information on integrity procedures for other membrane types. [8.1.7]
- Membrane integrity procedures developed by membrane system suppliers are typically set up to identify membrane failure and alarm at 4 log removal value (LRV) or a breach of 4 µm or greater. This is common international practice. [4.4, 8.1.5]
- The Guidance to the Regulations requiring '*continuous removing or retaining particles >1µm in diameter and where this process is subject to continuous monitoring* ' is being interpreted as absolute removal >1µm. Historically the membrane industry has operated under log removal values and, if a revised MIT is not feasible, then for practical reasons consensus agreement is needed to relate LRV to absolute removal. [8.1.1, 8.1.5, 8.1.13]
- Present PDT pressures are set to identify holes in the order of 4µm diameter. Setting the test to identify 1µm holes is theoretically possible but, for some membranes, it may not be practical. [8.1.7, 8.1.8, 8.1.14]
- The frequency of testing should be a pragmatic solution based on risk, economics, plant size and type of test. For the Pressure Decay Test and the Diffusive Air Flow Test, the frequency is generally related to the historic rate of fibre breakage. The frequency should be calculated on the risks of *Cryptosporidium* contamination in compliance with the standard. [8.1.8]
- Collaboration is needed between the system manufacturers and the water companies to develop acceptable membrane integrity test procedures based on guidance by the DWI. [8.1.4]

1.4.4 Objective 4

To draft generic solutions based on the results of initial assessments so that a standardised approach can be produced for each type of membrane.

- There are different membrane systems and a variety of membrane integrity tests. More information is needed to determine routine generic solutions. [4.4, 5.7, 8.1.7]
- Given current technology, any existing MIT system will not fully accord with the guidelines since current MIT procedures can only test the process <u>frequently</u>, but not continuously. [8.1.9]
- A daily test frequency would be consistent with the continuous sampling and analysis practice.
- If the absolute requirement was relaxed, the frequency of testing could be reviewed accordingly. [8.1.8]
- Intermittent monitoring at an appropriate frequency based on system design and risk of failure should be acceptable, although this will not meet fully the specified criteria as currently set. [8.1.8]
- Major conclusions from the site inspections:
  - All water companies welcomed the discussions on this new technology
  - Water companies do not fully understand the requirement to issue satisfactory proposals to the DWI
  - There are different interpretations of 'compliance dates'.
  - It would have been premature to conduct Audits under Section 86 of the Water Industry Act 1991.
  - Log removal values are being used as alarm and shutdown settings
- Some water companies are retaining bypasses. Procedures and authorisation for using such need to be in-place.[7.4]
- It is suggested that the responses to the audited criteria can be classed under five categories. [7.3]
- Revising a PDT to identify a 1μm breach in hollow fibre membranes is feasible. [8.1.7, 8.1.8, 8.1.14]
- DWI should update the guidance note to suggest that, until water companies adopt compliant integrity tests and mathematically define the MIT frequency at the appropriate sensitivity, the practical MIT frequency is recommended to be daily.

1.4.5 Additional conclusions and recommendations

The following are deemed important:

- DWI should consider single point of contact or a more structured approach to requests for *Cryptosporidium* information from water companies. [8.1.1]
- The progress if the ASTM protocol on membrane integrity testing should be kept under review. [4.4, 8.1.6]
- It is possible to monitor the product stream continuously for water quality parameters such as conductivity, particle count, colour etc., but this is not a direct MIT method and may not achieve the necessary sensitivity. [8.1.9]
- Future work should consider the membrane types not fully covered in this study, e.g. Degremont's Aquasource, AEA's Kerasep, etc. [8.1.3]
- DWI should encourage and support work to evaluate new membrane suppliers and

monitoring techniques that are expected to become available and approved for *Cryptosporidium* removal duty in the future. [4.4]

- DWI should convene an internal 'closed' workshop to discuss the issues arising from this report.

2 INTRODUCTION

2.1 Background

On 22 January 2001 DWI commissioned Consept to advise on the assessment of low-pressure membrane integrity monitoring proposals and operating strategies put forward by the water companies.

The Water Supply (Water Quality) (Amendment) Regulations 1999 came into force on 30 June 1999. Under the Regulations water companies were required to carry out risk assessments for each of their water treatment works to establish whether there was a significant risk from *Cryptosporidium* oocysts in the water entering supply. Over 300 sites in England and Wales were identified as having a 'significant risk' and water companies were required to submit proposals to DWI detailing their proposed monitoring programmes for approval.

DWI issued Guidance[2] on the type of treatment that could be installed and that would not require continuous sampling and monitoring under Regulation 23B. This specified '*Any treatment works in which all water passes through sufficient treatment plant capable of continuously removing or retaining particles greater than one micron diameter and where this process is subject to continuous monitoring and shutdown or turn out on failure'*. Further guidance on the DWI's interpretation of the treatment capability necessary to avoid continuous monitoring for *Cryptosporidium* was issued under DWI Information Letter 16/99. The DWI also commissioned an independent assessment of various membranes and membrane systems to demonstrate their capability of meeting the required criteria of absolute >1µm removal.

If a membrane system is installed, ideally there should be a continuous monitoring of filtrate quality to ascertain that the membrane is functioning effectively. However, there are currently no known on-line monitors other than those used for continuous sampling for *Cryptosporidium;* and current water quality monitors which measure surrogates such as turbidity monitors, particle counters and particle batch monitors are not considered robust, reliable or sensitive enough.

One advantage of using membrane technology is that, in routine operation, a non-destructive 'in-situ integrity tests' can be performed to check the membrane integrity. These MIT procedures are also attractive as they can be readily automated and are less dependent on operator intervention and expertise. Established routine MITs are undertaken off-line. At present, the design of membranes and membrane systems varies widely between different manufacturers and suppliers and this has resulted in a variety of membrane integrity tests. Continuous on-line membrane integrity monitoring is currently not a practical option, although new technologies may soon be available, e.g. acoustic sensors, on-line challenge tests, more sensitive particle counters.

As per the Guidance notes, water companies are required to demonstrate to the DWI that the MIT adopted at all sites where the membrane systems have been installed for

2 Guidance on assessing risk from *Cryptosporidium* oocysts in treated water supplies to satisfy the Water Supply (Water Quality) (Amendment) Regulations 1999 SI 1524

Cryptosporidium removal is suitable.

2.2 Objectives

A plan and programme of work was established with the following four objectives.

1. To define the criteria against which water company or suppliers' proposals for checking the integrity of drinking water treatment membranes would be evaluated.
2. To evaluate water companies' and suppliers' proposals for installation and operation of membranes and to advise on whether they meet with the defined criteria.
3. Where proposals are inadequate, to make recommendations for improvement.
4. To draft generic solutions based on the results of initial assessments so that a standardised approach can be produced for each type of membrane.

2.3 Methodology

The programme commenced on 24 January 2001 and was initially scheduled for completion on 31 July 2001. The activities to be undertaken are shown below:

- A desk study to review existing DWI approved products, comprising a review of existing product literature; published data and technical papers; plus completed supplier questionnaires.
- Assessment of existing membrane integrity monitoring procedures by contacting and visiting membrane manufacturers and suppliers.
- Submission of an interim report.
- Site visits to inspect and check the integrity monitoring systems at a number of operational installations.
- Assessment of all available data relating to current membrane systems, plus recommendations for any improvements will be made.
- Submission of this final report including all the above data, plus final recommendations proceeding to a set of generic requirements for membrane integrity testing for all DWI approved membranes.

The programme was subsequently amended and extended with a final scheduled completion on 31 October 2001.

2.4 *The* Programme Summary

The DWI commissioned the programme of work in January 2001. Consept commenced work on the programme in February 2001 and was initially scheduled to complete the project by 31 July 2001.

An interim report was issued on 24 May 2001. This report was based on the desk studies, membrane manufacturers and membrane system suppliers' information and the literature review.

The seven membrane companies that have membranes/systems approved under

Regulation 25 and also approval for *Cryptosporidium* treatment were approached for information on MIT.

Also seven water companies were approached for information on membrane treatment plants and their corresponding MIT procedures installed for *Cryptosporidium* treatment. Site inspections were carried out with three water companies to evaluate membrane integrity testing practices.

After these site inspections, correspondence and meetings were made with the membrane companies to further evaluate MIT details and limitations.

This has culminated in this final report, dated 31 October 2001, which reviews the current understanding, practice and operational performance of membrane integrity testing in the water industry and presents conclusions and recommendations for the way forward.

2.5 Membrane Approvals

There are two approval systems relevant to *Cryptosporidium.*

2.5.1 Approval for Use in Water Supply

Under Regulation 25 of the Water Supply (Water Quality) Regulations 1989[3] the Secretary of State and the National Assembly for Wales are charged with approving products and processes for use in public water supply. This is aimed at protecting public health and safety and does not evaluate their performance use. The Committee on Products and Processes (CPP) assesses products and processes and has approved a number of membranes and other filtration systems. It is important for users to differentiate the approval of products (membranes) and membrane systems since they are different.

2.5.2 Membranes meeting DWI criteria for *Cryptosporidium* removal

Water companies may install ‘appropriate’ treatment as an alternative to continuous sampling and monitoring of *Cryptosporidium* in water supplies. The main membrane processes designated for *Cryptosporidium* removal are microfiltration and ultrafiltration, which are both physical microporous separation processes. Other membrane types that can be used for the removal of *Cryptosporidium* include nanofiltration and reverse osmosis. The process performance of these membranes can be measured as an absolute particle removal or as a retention limit (c.f. log removal values on traditional filtration processes).

In order to give guidance on appropriate membranes and membrane systems approved as a appropriate treatment, the DWI appointed the Laboratory of the Government Chemist (LGC) to assess the CPP approved filtration products and processes as to their

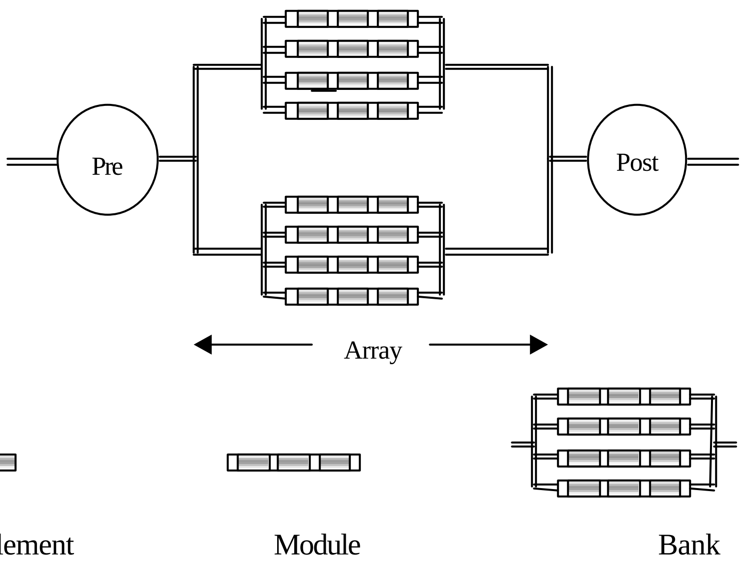
3 - Regulation 31 of the 2000 Regulations

capability of 'continuously removing or retaining particles greater than one micron diameter'. Meeting this criterion is considered sufficient and appropriate treatment for *Cryptosporidium* removal, as oocysts are typically 4-6 μm in diameter. As a result of the LGC assessments, the DWI has approved a number of membranes and membrane systems specifically for C*ryptosporidium* removal (see Appendix C).

3 MEMBRANE SYSTEMS

Membrane systems are modular in their nature and typical water treatment systems are constructed by building up from individual elements, to modules, to racks, to arrays and to full treatment systems as shown in Figure 3.1.

Figure 3.1. Typical Membrane Plant Illustrating a Treatment Train



3.1 Membrane Elements

- Hollow fibres membranes (*c*.18 types)
- Thin Film Composite (TFC) Spiral Wound membranes (*c*. 11 types)
- Tubular membranes (*c*.3 types)
- Ceramic membranes (*c*.2 types)

The seven approved membrane supply companies meeting the DWI criteria for *Cryptosporidium* removal as of 31 December 2000 are listed in Table 3.1 below. It should be noted that some of these suppliers only manufacture the membranes, some only supply treatment systems and some do both. Also, some companies license the use of their products/systems to other system suppliers.

There are many design and material differences within each of the basic types of membranes. They are manufactured in different ways and have different treatment capacities per module, different sizes and types of modules, different pore sizes, and so on. This makes generic rules very difficult and complex. The basic similarity is that they are physical filters.

Table 3.1. List of Approved Membranes/Filtration Systems for *Cryptosporidium* Removal (Note as dated 31 December 2000)

Company	Products and Processes
AEA Technology Ltd.	Kerasep - Cross Flow Filtration Module
Degremont UK Ltd.	Aquasource UF Membrane Module
Kalsep Ltd.	Kalmem Polyethersulphone Hollow Fibre Element
Koch Membrane Systems Ltd.	Targa Modules V and H TFC Membrane Elements 8131 UF Membrane Element
PCI Membrane Systems Ltd.	PCI Membrane Filtration System - Spiral Element PCI B1 Module and Membrane - Tubular Element 1 PCI Tubular C10 Module and Membrane System (incorporating Tubular Element 1)
US Filters Ltd.	CMF Continuous Microfiltration Systems M1 CMF Continuous Microfiltration Systems M2 CMF Continuous Microfiltration Systems M10
X Flow BV.	X Flow Membrane Filtration Elements

3.2 Membrane Modules

Generally, membrane elements are housed in a vessel enclosed at each end with end caps - this is defined as a module. However, some companies who manufacture hollow fibre membrane elements include the housing as part of the complete membrane element.

Spiral-wound, tubular and ceramic membranes each require a separate vessel. If vessels are used, they will contain additional components that can possibly fail and allow a potential breach by *Cryptosporidium*. In particular, the modules can contain seals and o-rings that can fail or allow leak.

Individual membrane modules need to be individually tested for integrity so that any fault (e.g. fibre break, fibre degradation, o-ring failure, glue failure etc) can be identified and the fault repaired.

3.3 Membrane Racks

Commercial membrane modules have relatively low treatment capacity. Thus a typical membrane treatment plant is constructed of many modules built into racks, arrays and treatment trains. These systems are modular in their construction, an increase in capacity of a membrane plant means an increase in modules, racks, arrays and treatment trains. A very large membrane plant can have hundreds, even thousands of membrane modules.

As these modules are grouped into racks, it is practical to first perform a MIT of a rack. If the rack passes then the individual membrane modules must be integral. If it fails, each module should be checked to identify the fault so that it can be repaired.

3.4 Membrane Trains

A membrane process 'train' is a series of modules and processes, which makes up a complete treatment process. A membrane based water treatment works may have several parallel process trains, which can be operated independently if required. It is possible to check a treatment train or the whole plant for integrity as a first course of action. If the whole plant fails an integrity test, then each section of the plant will have to be tested until the faulty module(s) is/are identified and rectified.

4 LITERATURE REVIEW

4.1 Method

An external search of international electronic databases was performed against key words, within a time period back to 1990. The first search produced a list of abstracts that the team then reviewed, selecting the most appropriate papers for retrieval. The retrieved papers were then reviewed and the most appropriate ones entered into the project literature database.

In addition to this review, information pertinent to this study was obtained from other reference sources (e.g. in-house, conference proceedings).

4.2 Review

The basis for the literature review has already been described. The review identified relevant information regarding membrane integrity testing, different concepts and operational histories from around the world to be described. A description of the basis and the review is presented in Appendix F.

4.3 Other findings

4.3.1 American Water Works Association Research Foundation (AWWARF)

A parallel two-year study into the subject of MIT has been initiated by AWWARF. It had been the hoped that some areas of common cause might have been described in this report. However, the AWWARF work has not yet progressed sufficiently. Perhaps, future study can address this issue.

4.3.2 American Standards for Testing Materials (ASTM)

In the US, ASTM Task Group D19.08.02 has recently (9 April 2001) issued a draft for review entitled, *Standard Practice for Integrity Testing of Membrane Systems.* The standard codifies some of the test methods that have already been described in this report - refer to Appendix I. It is anticipated that this draft, incorporating modifications, will be adopted in early 2002.

4.4 Conclusions

The review has considered literature that describes experiences from outside the DWI regulated area and the project team makes the following conclusions.

- There appears to be little long-term data or information on the subject of continuous monitoring of membranes able to remove particles greater than 1µm, product water quality and operational and maintenance requirements
- International practice commonly utilises log removal concepts to specify alarm set points and test frequencies. It is also common to test for fibre breaches (4µm and greater). These criteria do not currently accord with the DWI requirements.
- To our knowledge, there is no single MIT procedure referenced in the literature that will meet the DWI requirements.
- Each MIT should be system specific.

- A watching brief should be maintained on work to evaluate new membrane suppliers and monitoring techniques that are expected to become available and approved for *Cryptosporidium* removal duty in the future, e.g, acoustic sensors, on-line challenge tests, more sensitive particle counters.

5 MEMBRANE INTEGRITY TESTING - MEMBRANE COMPANY LEVEL

5.1 Membrane Integrity Testing Regimes

There are a number of different reasons why a membrane integrity test is performed on a membrane module or on a membrane system. For an operational plant there are reasons for routine operation and special cases operation. Non-operational MIT in full testing is carried out on pilot plants and quality control in manufacture. The following modes could all be considered reasons to carry out a test:

- Operational Plant Routine Control
- Monitoring Performance
- Following Clean or Maintenance
- Following Integrity Failure and Repair
- Operational Plant Special Case
- Commissioning New Plant or New Membranes
- Following Periods of Shut Down
- Research Exercise
- Specific Performance Analysis (Challenge Tests)
- Pilot Plant Testing
- Quality Control

This report focuses on those tests that are available to ensure that, whilst in operation, no particles > 1µm can pass through the membrane system into supply. The following two objectives are particularly important:

- To determine the integrity of membrane modules, membrane racks or membrane arrays.
- To locate any breach in the system.

5.2 Membrane Integrity Test Procedures

Membrane integrity tests can be classified as direct or indirect.

5.3 Direct Integrity Tests

These tests directly measure a breach in a membrane or membrane system. Direct tests monitor gas passing through a breach, filtrate flows, pressure changes or sound that can be detected. They include:

5.3.1 Pressure Decay Test (PDT) – Filled

This test involves applying pressurised air to the feed side to a predetermined level below the bubble point and then isolating. *(note: when the pores of a membrane are filled with liquid and air pressure is applied to one side of the membrane, surface tension prevents the liquid in the pores from being blown out by air pressure below a minimum pressure known as the bubble point).* The predetermined pressure directly relates to the size of defect under investigation.

The air pressure is monitored for a period of time (2 to 10 minutes) to observe the rate of decay. A small decrease of 0.1 or 0.2 psi per minute is considered acceptable and is due to diffusion of the air across the microporous membrane structure. A faster decrease in pressure indicates a faulty membrane. As the membrane system is open to atmospheric pressure on the filtrate side, the airflow can be observed to confirm the location of any breach. This method is capable of detecting changes in integrity at levels up to about 4.5 - 5 LRV.

5.3.2 Pressure Decay Test (PDT)– Drained

This is very similar to the 'Pressure Decay Test – Filled', but in this case the module is drained on both sides of the element so that the membrane is only "wetted".

5.3.3 Diffusive Airflow (DAF)Test

This test involves applying a constant feed side gas pressure below the bubble point of the selected size hole. The operator then measures the diffused gas filtrate flow or displaced water flow from the membrane. This test is fundamentally similar to the PDT but is capable of detecting integrity changes at levels > 6 LRV.

5.3.4 Acoustic Sensor

This test is based on hydrophonic sensor technology; the acoustic monitoring technique consists of measuring the noise due to a compromised filter. The advantage of a hydrophonic sensor is that integrity of the membranes is monitored continuously during filtration. The acoustic sensor is able to detect a non-cut compromised fibre and therefore, guarantees more than 6 log removal of viruses.

5.3.5 Audible Test – Stethoscope

In this test, an operator employs a stethoscope to manually listen to working modules to identify any sound produced by a breach in the membrane integrity.

5.4 Indirect Integrity Tests

These tests are indirect as they measure the result of a breached membrane system. Instruments monitor water quality by measuring inherent particles, introduced particles or turbidity.

5.4.1 Turbidity Monitoring or Reduction Monitoring

The turbidity of feed water and filtrate is monitored. An intact membrane would be expected to show a 90% reduction in turbidity from feed to filtrate. If the feedwaters were relatively clean, the differences in measurement would be beyond the capability of current turbidity meters.

5.4.2 Laser Turbidity Test

Similar to the above uses laser technology instead of light.

5.4.3 Particle Counters

A particle counter can count and monitor different sizes of particles in the filtrate. If the feed waters were relatively clean, differences in measurement would be beyond the limits of current particle counters.

5.4.4 Particle Batch Monitoring

The 'Particle Batch Monitor' is similar to the particle counter. It provides an index of the water quality rather than a particle count. It is cheaper than the particle counter.

5.4.5 Spiked Integrity Monitoring System - SIM™

This test doses high concentrations of powdered activated carbon (PAC) into the feed and measures the particulate levels in the product. This can be performed with the plant on-line. A log removal value can then be calculated.

5.4.6 MS2, Bacteriophage and Oocyst Challenge Tests

This test doses concentrations of microorganisms into the feed and measures the particulate levels in the product. This is basically a research tool and permits the calculation of log removal values for the specific organism.

5.4.7 Conductivity Tests

This test can be applied when the membrane removes significant amounts of dissolved ionic species. The product and feed waters will then have different ionic strengths/ conductivities. A defective membrane system will pass more ionic species; the conductivity instruments can identify such occurrences on-line. This test is therefore only relevant for reverse osmosis and nanofiltration membrane types.

5.5 Typical Times Taken for Integrity Test

It is important that the time taken to undertake a membrane integrity test is known in order to ascertain whether it is practical as a routine operational test. Most tests are completed in situ and off-line so the test time becomes down time or lost production time. Typical test times are summarised below.

Table 5.5. Typical Membrane Integrity Test Times

Membrane Type	Membrane Integrity Tests	Test Times	
		Module	Rack/Array
Microfiltration Ultrafiltration	Diffused Air Flow Test Pressure Decay Test – Filled Pressure Decay Test – Drained Audible Test – Stethoscope Acoustic Sensors Molecular Weight Cut Off Challenge Tests - microbiological Challenge tests - particle	15 minutes 10 minutes 10 minutes 1 minute Direct 2 hours 24 - 48 hours 30 minutes	Depends on number of modules per rack. Systems are generally automated
Nanofiltration	Conductivity Specific Ca and Mg Tests Challenge Tests - microbiological	Direct 1 hour 24 – 48 hours	Depends on number of modules per rack. Systems are generally automated
Reverse Osmosis	Conductivity (Dissolved Ions) Challenge Tests - microbiological	Direct 24 - 48 hours	Depends on number of modules per rack. Systems are generally automated

5.6 Review of membrane company information

The review of membrane company information covers the seven companies with membranes approved by the DWI for use in water supply and appropriate for *Cryptosporidium* treatment.

5.6.1 Information Collation

The companies were asked to submit any relevant information or published papers on existing proposals for membrane integrity testing. Information in the public domain has also been assessed. The response from the companies was very mixed. One membrane element/module manufacture company, AEA Technology, submitted no information and another, X-Flow BV, only submitted information on element/module testing. Both companies referred Consept to membrane system supply companies. Therefore, the information from these membrane system suppliers has been included under the membrane manufacturer.

Four of the membrane systems supply companies submitted standard procedures. One company employs another company's membranes submitted details on procedures that *they* were developing.

Two other membrane system companies working closely with membrane manufacturers and water companies have offered relevant information. They are Norit Membrane Technology (working with Yorkshire Water) and Environmental Resources Group (working with North of Scotland Water). This information has been included with the relevant membrane manufacturer.

General correspondence with the membrane companies is detailed in Appendix A. Specific information received from the membrane companies is detailed in Appendix D. The information has been categorised into the sub-sections listed below.

A summary of the findings appears in Table 5.7.

(i) Operational Plant Installations

The list of installations is derived from information sent to us from the membrane companies and the water companies. However, some responses did not identify specific sites.

(ii) Information Supplied

This section shows the variation in documentation forwarded to Consept.

(iii) Membrane Integrity Testing

This is separated into 'Element/ Module Test', 'Rack/Array and Whole Membrane System Test' and 'Membrane Integrity Testing Procedure'. All these aspects need to be assessed, as they accomplish different objectives, are different in complexity and require different procedures. The 'Identification of Breach and Repair' is part of the integrity process and should be identified in a protocol. In particular a repaired element/module or other rectification of a system should then be followed by an integrity re-test before re-commissioning the plant.

(iv) Continuous Monitoring System

This section is included, as this is the ideal solution for 24 hour monitoring of filtrate/final water quality. wo membrane system suppliers are evaluating continuous monitoring in their systems. The three common methods of continuous monitoring are all indirect surrogate methods of turbidity and particle measurement. A new direct method of acoustic sensing is discussed in the literature review; one overseas company is developing acoustic sensor methods.

(v) General Comments/Questions

This section raises issues and questions about the information.

5.7 Conclusions

The project team finds that:

- There are a number of MIT methods used for operational plant.
- The tests are specific for the type of membrane used and membrane system supplier.
- Most procedures employed at sites in the England and Wales derive from US membrane integrity procedures. i.e. they are based on log removal values.
- The most common MIT for capillary membranes is the Pressure Decay Test.
- Other test employed are Diffusive AirFlow Test and the Spiked Integrity Test - SIM™
- The membrane system suppliers are incorporating log removal criteria in membrane systems. Most water companies, although having the regulatory responsibility for their membrane and MIT systems, are passive towards determining suitable MIT systems.

6 CRITERIA FOR ASSESSING THE ADEQUACY OF MEMBRANE INTEGRITY TEST PROPOSALS TO MEET DWI REQUIREMENTS

6.1 Background

Membrane integrity testing procedures are very specific to each individual membrane or membrane system manufacturer. This is because although a basic element can be very similar in its appearance and structure, the material composition and operating environment are generally very different. For example, three system suppliers use the X-Flow BV hollow fibre membrane but each supplier offers a different MIT system.

Membrane element and module manufacturers believe they do not have a role or responsibility in measuring membrane integrity procedures on a system. They will test individual elements and modules for production quality control only and these procedures are required to locate faults. It is the membrane system suppliers who establish MIT procedures.

The tests share some common aspects and principles (e.g. PDT) but there are enough differences in the systems to regard them as different tests.

Although there is a great deal of information on performance of membranes, there is very little on operational MIT evaluation.

6.2 Membrane Integrity Proposals

The DWI Information Letter 16/99 instructed water companies to include "….details of the system to be used for monitoring the integrity of the membrane or other filter systems that they propose to install". It had been understood at the outset of this study that such proposals would have been issued to the DWI for each and every operational site where membranes are to be used as a barrier to *Cryptosporidium*. No existing membrane integrity proposals have yet been identified that address the regulatory requirement.

Water companies must have had their specific site MIT proposals agreed by the DWI before they can cease compliance monitoring at that site. Table 6.2 lists the minimum criteria that should be addressed in such proposals

6.3 Recommendations

- The DWI should ensure that MIT proposals are received and logged for each and every site where membranes are being installed as a barrier to *Cryptosporidium*.
- The DWI needs to make clear to the water companies exactly the type of information they wish to be included in such proposals. The water companies cannot then misinterpret the requirements.

Table 6.2 Criteria to be included in a MIT Proposal to the DWI

Topic	Criteria	Information Required
1 Ownership and Location	Responsibility: Membrane operation, Integrity testing, Water quality and Data management, Service and maintenance	Define site organisation structure identifying responsibilities
	Site name, Plant size and Control centre	State plant details and Control structure
	Source/Risk information	Describe source and specific site risks
2 Water Treatment Process	O&M manual	State existence and location of O&M Manual
	Whole treatment process diagrams	P&I diagrams required. Included in O&M
	By-pass	Details and management of by-pass.
3 Monitoring	On line instrumentation, Parameters and Data logging	State any online monitoring additional to the MIT (i.e. auxiliary monitoring) Include alarm and any shut down/trip settings, e.g. turbidity, particle counting
4 Membrane Process	Membrane flow diagrams	P&I diagrams required. Included in O&M
	System supplier, Membrane type	State membrane system supplier, membrane type
	Regulatory approvals	State details of regulatory approvals/consents (i.e. DWI CPP approvals, *Cryptosporidium* approval list and Environment Agency Discharge consent)

➢Continued overleaf

Topic	Criteria	Information Required
5 Membrane Integrity System	Membrane element type	Description required, e.g. Hollow fibre, Spiral Wound or Tubular and UF, MF, NF or RO
	Name of Test and Description	Name and describe MIT
	Basis of Test to meet *Cryptosporidium* regulations	Describe basis of test to meet regulations.
	Test initiation (Manual/automatic)	Description required
	Test Settings	Description required
	Alarm and Shut down/Isolation settings/procedures	Description required
	Frequency and Justification	Description required
	Automatic/Manually shut down/isolation settings and procedures.	Description required
	Identification of breach/failure, isolation, repair/replacement, spares and re-commissioning	Description required
6 Telemetry	Arrangements for onsite/remote monitoring	Description required to explain continuous monitoring
7 Data & Information	Data Management and Information Reporting	Description of data management, recording, storage duration and information reporting
8 Other	Additional relevant information, e.g. Training comments	Additional relevant information.

7 MEMBRANE INTEGRITY TESTING - WATER COMPANY SITE INSPECTIONS

7.1 Introduction

It had been envisaged that MIT proposals would be available from those water companies who had either installed or were planning to install membrane plant for *Cryptosporidium* removal. Up to twenty sites were identified for audit but since the DWI had not received any such proposals against which such an audit could be performed, a new approach was adopted that involved meeting and having open discussions with a number of the water companies.

This approach was then followed by inspections at three sites where membrane systems had been installed

The purpose of this exercise was to evaluate their understanding of the DWI requirements, evaluate any MIT being undertaken or proposed, and gather information on any procedures relevant to the proposals.

A 'Summary of Water Company Correspondence' is presented in Appendix B.

7.2 Discussions of MIT Proposals with Water Companies

7.2.1 Background

A number of water companies were contacted that were planning to install membrane plants as part of the *Cryptosporidium* Regulations or had plants that were operational. The companies were selected so that different membrane types, systems, and plant sizes could be evaluated.

The companies generally included their operational personnel, DWI liaison, process / technical development personnel in the meeting. In five of the seven meetings, a representative from the membrane system supplier also attended.

In most cases, it was clear that water company personnel had not grasped the full relevance of MIT testing in relation to the regulatory requirements. Any MIT procedures in place were taken from the membrane suppliers and not adapted to ensure that the criteria specified in the guidance notes were being met.

7.2.2 Meetings

The meetings were held with seven water companies:

- South West Water Services
- Severn Trent Water
- Thames Water Utilities
- United Utilities
- Bristol Water
- Northumbrian Water

- Yorkshire Water Services

The agenda for the meetings followed the criteria listed in Table 6.2.

One other company, Three Valleys Water plc, declined the project team's request to meet for informal discussions.

7.2.3 Summary of Discussions

The meetings were welcomed by all parties and fostered open discussion of the water companies' experiences with membrane plant and, in particular, MIT procedures. The water companies were made aware of the regulatory requirements.

The meetings elicited useful information for sites both in planning, and in operation. This data is summarised in the next section.

Section 7.3 discusses the inspections of the three operational sites.

7.3 Site Inspections

7.3.1 Background

The three sites selected for site inspection were:

- Alderley, Bristol Water plc
- North Orpington, Thames Water Utilities Ltd
- Clay Lane, Three Valleys Water plc

7.3.2 Methodology

The site inspections followed the proposed framework. The framework can be developed and adopted for use in future routine audits.

Table 7.3 Framework for Audit Questionnaire

Section	Topic	Comment
1	Site Overview	Location, Type of source, Source protection, Supply Zone, Manning, Responsibilities, etc
2	Membrane System	Description, Reg 25, Backwash arrangements, Discharge, Maintenance arrangements, etc
3	Water Treatment Process	Description, Flow diagram, By pass, Alternative supply arrangements, etc
4	Disinfection System	Description
5	Monitoring	Policy, Procedures, Intermittent, Continuous, Alarm settings/Shut down, etc
6	Membrane Integrity Testing	MIT Policy, Procedures, DWI Proposal, Description, Manual/Auto, Frequency and Duration of Tests, Alarm and action, isolation, Identification, Repair and Recommissioning, Training, Maintenance etc
7	Telemetry	Policy, SCADA, Control Centre
8	Data Management and Information	Policy, On site, Control Centre, Storage, Analysis, Regular reporting etc
9	Other	

Please refer to the separate document entitled *Final Report - Site Inspections* for full details of the inspections at each of the above sites.

In future audits, it is suggested that the responses to the criteria can be classed under the following general categories:

- **Category 1 –** No MIT proposal. No supporting evidence provided or seen. Audit failure of the set criteria.

- **Category 2 –** Inadequate MIT proposal. Evidence seen, or supporting documentation produced, but is inadequate, incomplete, or otherwise fails to achieve the “satisfactory” objective.

- **Category 3 –** With some improvement or modification, able to achieve "satisfactory". The audit fails to produce a "satisfactory" result; but it has been observed or supporting evidence provided that the water company has made progress to comply with the DWI objectives.

- **Category 4 -** Evidence seen or produced to satisfy the set criteria.

- **Category 5 –** Unable to rate as Satisfactory or Failed. Requires further clarification or guidance regarding definition or interpretation. This may be subject to results of work planned or in progress.

7.3.3 Comments

The site inspection exercise confirmed that water companies do not understand the requirement to issue satisfactory proposals to the DWI describing the MIT procedures to be adopted at a specific site. There is also a misunderstanding on the issue of compliance dates.

Clarification is also needed as to whether the MIT is part of the approval mechanism. It is considered that some parts of the water industry assume that the MIT is part of the approval process.

However, it was useful to 'test' the proposed audit questionnaire in a real environment, and check the understanding and adoption of the suggested minimum criteria for an MIT proposal (see Table 6.2). At present, no company satisfies all the areas, although the site inspections, previous meetings with the water companies, and future proposed guidance from the DWI should address any omissions.

The questionnaire can be developed for Audit purposes.

7.4 Conclusions

- Statements of Intent and the implementation programme are still changing as water companies review their options.
- The main membrane system suppliers are NMT, Kalsep, Memcor and PCI - Water. All four contractors to date have employed hollow fibre membranes. All use their own designed MIT tests.
- Some companies are retaining by-passes. Procedures and authorisation for using such need to be in-place.
- The main types of test being employed are the Pressure Decay Test and the Diffusive Airflow Test. Particle counting often augments these tests.
- In addition, an on-line challenge test, the SIM™ test, is operational at one site, Yorkshire Water's Keldgate facility.
- The frequency of testing varies between daily, 72 hrs or longer. The frequency is often set using a log removal criterion of 4 to 5.
- For the MIT test, the alarm and shut down settings typically relate to a 4µm breach. On larger plants, the alarm and shut down settings often relate to a log removal value of 4.
- Some companies will set alarms against other measured variables, e.g feed

turbidity, high pH in treated water.

- Data is generally logged and recorded both locally and at the control centre (by telemetry). Data will be kept between 2 – 5 years.
- Identification, isolation, repair and re-commissioning procedures are set in operating manuals. Currently, there is very little experience in the UK water industry.
- The framework detailed in the *Final Report - Site Inspections* document needs to be trialled and developed further.
- From the limited number of site inspections performed, it is anticipated that once plants have been transferred from Commissioning to Operations, the water companies will be able to write MIT proposals encompassing most of the criteria listed in Table 6.2. However, DWI should give the water companies before they can issue a complete MIT proposal; see Table 8.2. The proposals can then be fully validated and tested.
- Clarification is also needed as to whether the MIT is part of the CPP approval mechanism. It is considered that some parts of the water industry assume that the MIT is part of the approval process.

8 DISCUSSION OF ISSUES

This section identifies issues that have arisen from discussions with system suppliers and the water companies.

8.1.1 The *Cryptosporidium* Regulations

The DWI requirement is for the continuous *removal or retention of particles greater than 1µm* and this is interpreted as an absolute removal. Membrane suppliers have generally developed MIT procedures based on 4-5 LRV. If a LRV is stated, then in order to be meaningful, this value needs to be related to a particular particle size or particle size distribution. In the main, membrane systems only have a single barrier. The detection of the failure of this single barrier requires that an effective MIT system at an acceptable frequency is used.

Is the expectation that complete removal of particles > 1µm practical, and is this consistent with the *Cryptosporidium* standard < 1 oocyst / 10 litres?

Water companies appear to use several contacts at the DWI to discuss *Cryptosporidium* issues.

<u>Comments</u>:

- *DWI needs to debate whether compliance should be based on absolute 1µm particle removal or whether log removal criteria can be used.*
- *DWI should consider a single point contact or more structured approach to requests for information.*

8.1.2 Approved Membranes/Systems for *Cryptosporidium* Removal

Approval covers the membrane element or membrane system. The membrane manufacturers, system suppliers and the water companies need to understand the approval mechanism. The criteria LGC uses to accept 1 µm removal for approval of membranes needs to be determined and this will help to keep consistency in the approach for MIT testing. See extract from LGC report Appendix H.

<u>Comment</u>:

- *Water companies need to understand whether Regulation 25 Approvals are for the membrane element or the membrane system.*
- *Clarification is needed as to whether the MIT is part of the approval mechanism. Some parts of the water industry assume that the MIT is part of the CPP approval process included in the 'Instruction for Use'.*

8.1.3 Responsibility of MIT and MIT Proposals for Water Treatment System

The water companies need to recognise that the requirement of paragraph 14 of the Guidance to the Regulations (refer to Information Letter 16/99) covers broader issues that the basic MIT itself.

The DWI membrane list includes seven registered holders having approval for their membrane elements and membrane systems. Each type of approval holder has a different interest in integrity testing and this is reflected in the information supplied on request.

AEA Technology and X-Flow BV only manufacture the basic elements and modules respectively. As a consequence, they appear to have little interest and information on integrity testing system procedures, apart from the testing of their basic membrane/ modules. X-Flow BV claims that system membrane integrity testing is not their business.

Degremont UK Ltd, Kalsep Ltd, Koch Membrane Systems and US Filters Ltd all manufacture membranes within their group of companies. They also build and install membrane systems. They, therefore, have an interest in single membrane module integrity testing and membrane system integrity. These four companies are well established in the membrane application field and have developed individual standard procedures for MIT on their approved products.

PCI - Membranes has approved membranes but it is their sister company, PCI-Water, who is supplying and installing membrane plants for the removal of *Cryptosporidium*. They are using X-Flow approved membranes at Thames Water's North Orpington facility and, as a newcomer to this field, are developing their own independent integrity systems. Future systems will employ Kalsep membrane supplied by Hydranautics.

Degremont UK has been awarded a contract to install Aquasource membrane at Northumbrian Water's Tosson site; this will represent the only *Cryptosporidium* facility with this type of membrane in England and Wales.

Hydranautics is a US membrane manufacturer that also supplies systems. In the UK they are supplying Kalsep (the Kalmem system) and they are supplying PCI- Water via an arrangement with Kalsep.

The membrane manufacturer X-Flow BV has a sister company, Norit Membrane Technology, who build and install membrane systems. This group is developing a novel membrane integrity system in conjunction with Yorkshire Water.

ERG is using AEA's ceramic membrane, Kerasep, in a *Cryptosporidium* treatment facility for the North of Scotland Water Authority. Rhodia-Orelis SA, a French company is working with ERG to developing suitable integrity test systems. This system has not been investigated in this study.

Comment:

- *Membrane manufacturers show little interest in MIT for a system.*
- *The international market (where LRV criteria are widely specified) influences systems specified in England and Wales.*
- *There is a need for the system suppliers to work with the companies to arrive at integrity testing systems that meet the regulatory requirements.*
- *The water companies have the final responsibility for their own MIT Proposals. Future work should consider the membrane types not fully covered in this study, e.g. Degremont's Aquasource and AEA's Kerasep.*

8.1.4 Collaboration of Stakeholders

In order to develop suitable membrane integrity systems and operating strategies to meet regulatory and water company requirements, the system manufacturers and the water companies must work in collaboration to identify the necessary proposals based on guidance by the DWI.

Comment:

- *All parties need to work together*

8.1.5 Log Removal Value

Leading on from the work undertaken by Panglisch (see Appendix F), LRV values can be calculated based on system size. For plants containing a relatively small number of modules, the detection of a single fibre break constitutes a calculated log removal value of less than 4. Larger plants containing a greater number of modules will have calculated log removal values in excess of 4 but less than 5.

Comment:

- *Basis of LRV for MIT leads back to the Panglisch work. This is seen as a pragmatic approach internationally.*

8.1.6 ASTM MIT Protocol

In the US, an ASTM protocol for MIT has been drafted. A version of this is included for information only - Appendix I.

Comment:

- *The ASTM protocol should be kept under review.*

8.1.7 Current Operational Membrane Integrity Test Failure Alarm Settings

Current MIT systems for capillary membranes are typically set to alarm against parameters based on:

- Absolute size removal (4µm and greater)
- Particle log removal value (4-5 LRV)

These criteria reflect the international position but do not satisfy the regulatory requirements for >1µm absolute removal.

Higher starting pressures for the test would enable smaller defects (e.g. 1 µm) to be detected thereby satisfying the current requirements. However, the higher start pressures may cause some membranes to experience higher defect rates than are currently assumed.

There is little information on other membrane types though it should be noted that thin film composite membrane systems are able to have their system integrity continuously measured using conductivity readings. Table 8.1.7 provides a summary of MIT procedures and typical alarm levels.

<u>Comment:</u>

- *There is a need for the system suppliers to work with the companies to arrive at integrity testing systems that meet the regulatory requirements.*

Table 8.1.7 Summary of Operational Membrane Integrity Tests

Membrane System Type	Operational Status		Use for *Cryptosporidium*	Comment
Capillary Hollow Fibre	a)	Pressure Decay Test	Commonly used for *Cryptosporidium* removal	Typically set for 4µm or 4 log removal
	b)	Challenge Test using Particle Counters	New system - rarely used SIM™	Typically set for 4 log removal
	c)	Diffusive Air Flow Test	Used in large plants.	More sensitive than PDT, 5-6 LRV
	d)	Particle Monitoring	On-line back up system	Unreliable in operational range
Thin Film Spiral Wound	a)	Conductivity Test	No sites identified for *Cryptosporidium* removal	On-line test
	b)	Particle Monitoring	On-line back up system	Unreliable in operational range
Ceramic	a)	Pressure Decay Test	No sites identified for *Cryptosporidium* removal	Insufficient information
	b)	Particle Monitoring	On-line back up system	Unreliable in operational range
Tubular	a)	No MIT test information submitted	No sites identified for *Cryptosporidium* removal	
	b)	Particle Monitoring	On-line back up system	Unreliable in operational range

8.1.8 Current Operational Membrane Integrity Test Frequencies

The established system suppliers for hollow fibre membrane have standard membrane integrity test procedures, utilising variations on the PDT and DAF Test to identify breaches in the hollow fibres. These tests are intermittent and are performed in situ and offline. The tests are undertaken on racks or arrays; they are generally automatic and alarmed to raise operator intervention. The operator must then manually find the fault and rectify the problem. The plant must be capable of this regular shut down to enable testing to be undertaken.

The tests are completed at varying frequencies. There is a lack of justification in the frequency of testing, sometimes it is once a day, sometimes after a clean or at another time period.

Daily test frequencies should be beneficial when ascertaining system integrity. However, a daily frequency may cause some membranes to experience higher defect rates than are currently assumed.

MIT frequencies need to be related to a risk assessment as the first priority and operational practicality as the second priority.

<u>Comment:</u>

- *Membrane systems should have sufficient design capacity to maintain design output, e.g. in order to cope with the modules and arrays being taken out of production during off-line MIT procedures.*
- *The information received from the membrane companies is focused on the <u>test</u> and not the overall <u>procedure/proposal</u>.*
- *Hollow fibre membranes are the favoured option for Cryptosporidium removal, and the MIT itself is well established, though based on international practice.*
- *There needs to be an assessment of the MIT frequency that is determined by a risk assessment.*
- *If DWI relaxed the absolute requirement, the frequency of testing could be reviewed accordingly*
- *There are a few generic principles for membrane integrity monitoring but details will be specific to a particular site.*

8.1.9 Adequacy of Existing Membrane Integrity Testing

The existing MITs do not meet the regulatory requirement and are based on common international practice, e.g. testing for log removal rather than absolute removal. There are certain aspects that need to be addressed:

- There are no common guidelines for the frequency of MIT tests.
- Requirement for continuous monitoring is not possible at present for operational plant.
- Procedures need to be revised with inputs from water companies.
- Systems developed by membrane system suppliers have Intellectual Property Rights on certain aspects of membrane integrity monitoring. These may prevent a recommended benchmark procedure from being used in competitor systems.
- Different membrane systems can employ the same membrane elements though the MIT methods vary.

<u>Comment</u>:

- *Present MIT systems are not developed adequately for regulatory requirements.*
- *It is also unlikely that given current technology, any existing MIT system will fully accord with the guidelines since current MIT procedures can only test the process <u>frequently</u>, but not continuously.*
- *It is possible to monitor the product stream continuously for water quality parameters such as conductivity, particle count, colour etc., but this is not a direct MIT and currently will not achieve the necessary sensitivity.*

8.1.10 New Membrane Integrity Procedures

Some membrane system suppliers are developing new procedures and new methods in collaboration with water companies in order to set out proposals under the *Cryptosporidium* Regulations.

<u>Comment</u>:

- *Membrane system suppliers are working on new MIT systems utilising log removal criteria but they need to consider the DWI Guidance notes to the Regulations.*

8.1.11 Membrane Integrity Test Proposals

A number of factors affect the formulation of an MIT proposal:

- The size, criticality and redundancy of the water treatment system.
- The overall integrity of the water treatment system.
- The adoption, by membrane system suppliers, of previous international MIT procedures.
- Guidance is needed for water companies as to what should be included in a MIT proposal.
- System components of the water treatment system need to be identified so that the integrity of the whole system can be audited.

Ideally the whole treatment train should be continuously monitored for breaches in integrity. This is going one step further than membrane module, rack or array integrity testing.

Membrane integrity tests can in simple terms be generic, but once site procedures are incorporated, they can become site-specific.

Any MIT proposal needs to meet both operational needs and DWI compliance needs.

Comment:

- *There is a need for the DWI to set guidance as to what should be included in an MIT proposal (see Table 6.2).*
- *It should be recognised that an MIT proposal is broader in scope than a simple MIT test procedure.*
- *Water companies and membrane system suppliers need to work together to develop suitable MIT tests that comply with the regulatory requirements.*

8.1.12 'By passing' of the Membrane Treatment Train

The issue of allowing a by-pass around the membrane was raised several times.

Comment:

- *DWI to issue guidance that bypasses can only be retained if the means to perform continuous compliance monitoring is retained.*
- *The guidance should also advise of the fail-safe protection devices required when bypass lines are present.*

8.1.13 Capillary Breakages

Absolute removal of particles greater than 1µm would be compromised with a single fibre break in a plant whatever the plant's size. This means that a small plant would not be expected to fail as often as a large plant which having a larger number of fibres, has a greater probability of a single fibre breaking. Logic suggests that a single failure in a larger plant should pose a smaller threat to public health than a single failure in a small plant. Only on an equivalent percentage fibre break basis would one expect the risk to be equal.

Given a history of breakage rates, the expected number of fibre failures per plant per year can be calculated. Given a LRV target, the MIT frequency can then be calculated based on a simple model or a statistical model. A 4-LRV target could be proposed for waters with >10,000 oocysts/10 litres; a treated water would then have < 1 oocyst/10 litres, a figure that corresponds to the regulatory target.

Comment:

- *Present PDT will detect a single fibre breakage albeit with a hole of 4ìm. This is a breach of the current guideline on the 1µm absolute barrier.*
- *Detection of a single break in a small plant can be significant.*
- *A single break in a large plant corresponds to a higher LRV target than a single breakage in a small plant.*

8.1.14 Pressure Measurement for Capillary Membranes

For capillary membranes the starting pressure and pressure drop in PDTs over time should be based on experimental work by the membrane suppliers. Such experimental work will probably be based on bubble point pressures calculated for the particular membrane type and assuming a defect size of 4 µm. It should be noted that the theoretical bubble point pressure of the membrane itself is likely to be greatly in excess of this figure. However, starting pressures based on a 1µm defect will be four times as great as those will for a 4µm defect. The pressure drop over time will also be greater, possibly enabling larger systems to be tested without loss in sensitivity. The mechanical design of the system will have to accommodate this higher pressure - increased capital costs would be likely. Tests based on a defect size greater than 1µm, will not detect defects down to 1µm.

Pressure measurement sensitivity enables a limit to be placed on the size of the total system subset. The larger the rack, the greater the dilution effect, and the lower pressure drop (airflow) over time.

Comment:

- *Present PDT pressures are set to identify holes in the order of 4µm. Setting the test to identify 1µm holes is theoretically possible but, for some membranes, it may not be practical.*

8.1.15 Data Management

Water companies should retain MIT data for trending.

MIT criteria are derived from experimental work into systems where fibres are intentionally compromised. The test is then set to reflect a single fibre failure. This measured variable (e.g. PDT) can then be use to calculate the LRV for the subset of the total system which has undergone the MIT. Trending of this value is recommended to assist in monitoring the long-term performance of the plant. The MIT frequency can then be adjusted in the light of operational experience.

Comment:
- *Water companies can learn from trending of data*
- *The project team recommends that the DWI consider a requirement that water companies regularly trend MIT data.*
- *The project team recommends that the DWI consider a requirement that water companies store trended MIT data for a minimum of 5 years.*

8.2 Conclusions/ Summary of Comments

8.2.1 The Regulations and Approved Membranes

- DWI needs to debate whether compliance should be based on absolute 1µm particle removal or whether log removal criteria can be used.
- DWI should consider a single point contact or more structured approach to requests for information.
- Water companies need to understand whether Regulation 25 Approvals are for the membrane element or the membrane system.
- The industry appears to be confused between the approval for Regulation 25 and the approvals for the *Cryptosporidium* list.
- Clarification is needed as to whether the MIT is part of the approval mechanism. It is considered that some parts of the water industry assume that the MIT is part of the approval process.
- Present MIT systems are not developed adequately for regulatory requirements.
- It is also unlikely that given current technology, any existing MIT system will fully accord with the guidelines since current MIT procedures can only test the process frequently, but not continuously.
- DWI to issue guidance that bypasses can only be retained if the means to perform continuous compliance monitoring is retained.
- The guidance should also advise of the fail-safe protection devices required when bypass lines are present.

8.2.2 Membrane Integrity Test Regimes

- The international market (where LRV criteria are widely specified) influences systems specified in England and Wales.
- Hollow fibre membranes are the favoured option for *Cryptosporidium* removal, and the MIT itself is well established, though based on international practice.
- Membrane manufacturers show little interest in MIT for a system.
- Membrane system suppliers are working on new MIT systems utilising log removal criteria but they need to consider the regulatory requirements.
- There are common generic principles for membrane integrity monitoring but specific site system details will be different.
- Higher starting pressures for the test would enable smaller defects (e.g. 1 µm) to be detected thereby satisfying the current requirements. However, the higher start pressures may cause some membranes to experience higher defect rates than are currently assumed.
- Daily test frequencies should be beneficial when ascertaining system integrity. However, a daily frequency may cause some membranes to experience higher defect rates than are currently assumed.
- Membrane systems should have sufficient design capacity to maintain design output, e.g. in order to cope with the modules and arrays being taken out of production during off-line MIT procedures.

8.2.3 Membrane Integrity Test Proposals

- The information received from the membrane companies is focused on the <u>test</u> and not the overall <u>procedure/proposal</u>.
- There is a need for the system suppliers to work with the companies to arrive at integrity testing systems that meet the regulatory requirements.
- There needs to be an assessment of the MIT frequency that is determined by a risk assessment.
- If 1µm looked on as an absolute, then daily testing but if DWI relaxed the absolute requirement, the frequency of testing could be reviewed accordingly.
- The water companies have the final responsibility for their own MIT Proposals.

8.2.4 Other matters

- The ASTM protocol should be kept under review.
- It is possible to monitor the product stream continuously as a water quality parameter such as conductivity, particle count, colour etc., but this is not a direct MIT and might not achieve the necessary sensitivity.
- Basis of LRV for MIT leads back to the Panglisch work. This is seen as a pragmatic approach internationally.
- Present PDT pressures are set to identify a single fibre breakage albeit with a hole in the order of 4µm. Setting the test to identify 1µm holes is theoretically possible but, for some membranes, it may not be practical.
- A single break in a large plant corresponds to a higher LRV target than a single breakage in a small plant.

- Water companies can learn from trending of data
- The project team recommends that the DWI consider a requirement that water companies regularly trend MIT data.
- The project team recommends that the DWI consider a requirement that water companies store trended MIT data for a minimum of 5 years.

The following table summarises the team's proposed guidelines for MIT.

Table 8.2: MIT Guidelines for Membrane Plant installed to remove *Cryptosporidia*

Topic	Criteria	Recommended Guidelines
1 Ownership and Location	Responsibility: Membrane operation, Integrity testing, Water quality and Data management, Maintenance and Service Arrangements	Detail specific responsibilities for site and data management.
	Site name, Plant size and Control centre	Detail specific site information.
	Source/Risk information	Detail specific causes of significant risk and consider management systems.
2 Water Treatment Process	O&M manual	Located on site.
	Whole treatment process diagrams	Included in O&M manual
	By-pass	No by-pass if possible.
3 Monitoring	On line instrumentation, Parameters and Data logging	Other continuous parameter(s) logged (e.g. Turbidity) on raw water feed for intake protection and or supporting information.
4 Membrane Process	Membrane flow diagrams	Included in O&M manual
	System supplier, Membrane type	
	Regulatory Approvals	Membrane system to have CPP approval. Membrane element/module to have *Cryptosporidium* approval.

➢Continued overleaf

Topic	Criteria	Recommended Guidelines	
5 **Membrane Integrity System**	Membrane Element Type	Hollow Fibre (MF & UF)	Spiral Wound (NF & RO) Source dependent
	Name of Test and Description	Pressure Based Tests (e.g. PDT and DAF).	Conductivity Based Tests
	Basis of Test to meet *Cryptosporidium* regulations.	Aim to test for 1µm defect. Statement required on what defect size is detectable with test. Setpoints for each train to be stated.	The settings should be based on sound empirical evidence.
	Test Initiation (manual/automatic)	Automatic required with manual override facility	Automatic with manual override facility
	Test settings.	Based on empirical evidence. Specific for each type, manufacturer and configuration of membrane.	Specific for each type, manufacturer, configuration of membrane and feed water quality.
	Alarm and Shut down/isolation settings/procedures	Should include an alarm/warning point. For shut down/isolation the minimum requirement is 4 LRV of 1µm particles (a) 4 LRV of particles greater than1µm for the PDT and (b) 5 LRV of particles greater than1µm for the DAF test.	The settings should be based on sound empirical evidence.
	Frequency and Justification	Daily testing.	Online and continuous
	Automatic/Manually shut down/isolation	Automatic required with manual override facility	
	Identification of breach/failure, isolation, repair/replacement, spares and re-commissioning procedures.	All these procedures to be fully described and easily executed by operating personnel	
6 **Telemetry**	Arrangements for onsite/remote monitoring	Unmanned sites to utilise telemetry	
7 **Data & Information**	Data Management and Information Reporting	MIT process parameters stored for 5 to 7 years or as long as the membrane element warranty. Parameters to include start test pressure, relevant measured variable over the test period.	MIT process parameters stored for 5 to 7 years or as long as the membrane element warranty. Minimum guideline is storage of daily averages.
8 **Other**	Additional relevant information, e.g. Training comments	Additional relevant information, e.g. Operational training in place.	

9 CONCLUSIONS AND RECOMMENDATIONS

Objective 1: To define the criteria against which water company or suppliers' proposals for checking the integrity of drinking water treatment membranes would be evaluated.

- The criteria required in a MIT proposal has been identified and listed in Table 6.2 of this report. [6.2]
- DWI should produce a detailed guidance note for water companies to assist development of MIT proposals. See Table 6.2 and, in particular, section 5 thereof.
- DWI should publish specific principles and update the guidance note. See Table 8.2.
- Water companies must have had their specific site MIT proposals agreed by the DWI before they can cease compliance monitoring at that site. [6.2, 7.3]
- DWI should clarify those aspects of CPP approval where it covers membrane elements or membrane systems.
- DWI should clarify the criteria employed by the LGC to determine the 1ìm absolute removal so that a consistent approach is taken (see Appendix H).
- There are different interpretations of the 'compliance dates'. [7.3]

Objective 2: *To evaluate water company and suppliers' proposals for installation and operation of membranes and to advise on whether they meet with the defined criteria.*

- No existing proposals have yet been identified that adequately routinely monitor membrane integrity on water companies' operational sites. [7.1]
- Water companies differ in their interpretation of the DWI requirement. A well-defined guidance note is needed to ensure that companies produce adequate and consistent information that can then be used to benchmark comparisons. [8.1.11]
- Some water companies have assumed that CPP approval for membranes indicates that the MIT has been approved under 'instructions for use'. [7.3, 8.1.2]
- Membrane elements, membrane system configurations and MIT procedures differ. At this stage it is not possible to produce generic guidelines. [4.4, 5.7]
- Responsibility to produce acceptable proposals rests finally with the water companies. Companies installing membrane systems will need to ask the manufacturers/ suppliers to provide full details of their system of monitoring the integrity of the filtration system and adapt them to meet operational requirements. [5.7, 8.1.3]
- The water companies will also need to assess whether these procedures are adequate for the system design and, if so, integrate them into site specific procedures at each treatment works. [8.1.3, 8.1.10]
- The DWI guideline requiring continuous process (membrane integrity test) monitoring of an "absolute 1µm barrier" is not feasible with current technology. [8.1.1, 8.1.7, 8.1.13, 8.1.14]
- From the limited number of audits performed, it is anticipated that once plants have been transferred from commissioning to operations, the water companies will be able to refine MIT proposals encompassing most of the criteria listed in Table 6.2. However, DWI should give the water companies guidance before they can issue a complete MIT proposal; see Table 8.2. The proposals can then be fully validated and tested. [6.2, 7.4, 8.2]

Objective 3: *Where proposals are inadequate, to make recommendations for improvement.*

- The Proposals should address all the criteria in Table 6.2 and, in particular, section 5 thereof. [6.2]
- Hollow fibre membrane integrity procedures are well developed but need to be adapted and incorporated into company specific proposals. There is a paucity of information on integrity procedures for other membrane types. [8.1.7]
- Membrane integrity procedures developed by membrane system suppliers are typically set up to identify membrane failure and alarm at 4 log removal value (LRV) or a breach of 4 µm or greater. This is common international practice. [4.4, 8.1.5]
- The Guidance to the Regulations requiring '*continuous removing or retaining particles >1µm in diameter and where this process is subject to continuous monitoring* ' is being interpreted as absolute removal >1µm. Historically the membrane industry has operated under log removal values and, if a revised MIT is not feasible, then for practical reasons consensus agreement is needed to relate LRV to absolute removal. [8.1.1, 8.1.5, 8.1.13]
- Present PDT pressures are set to identify holes in the order of 4µm diameter. Setting the test to identify 1µm holes is theoretically possible but, for some membranes, it may not be practical. [8.1.7, 8.1.8, 8.1.14]
- The frequency of testing should be a pragmatic solution based on risk, economics, plant size and type of test. For the Pressure Decay Test and the Diffusive Air Flow Test, the frequency is generally related to the historic rate of fibre breakage. The frequency should be calculated on the risks of *Cryptosporidium* contamination in compliance with the standard. [8.1.8]
- Collaboration is needed between the system manufacturers and the water companies to develop acceptable membrane integrity test procedures based on guidance by the DWI. [8.1.4]

Objective 4: *To draft generic solutions based on the results of initial assessments so that a standardised approach can be produced for each type of membrane.*

- There are different membrane systems and a variety of membrane integrity tests. More information is needed to determine routine generic solutions. [4.4, 5.7, 8.1.7]
- Given current technology, any existing MIT system will not fully accord with the guidelines since current MIT procedures can only test the process frequently, but not continuously. [8.1.9]
- A daily test frequency would be consistent with the continuous sampling and analysis practice.
- If the absolute requirement was relaxed, the frequency of testing could be reviewed accordingly. [8.1.8]
- Intermittent monitoring at an appropriate frequency based on system design and risk of failure should be acceptable, although this will not meet fully the specified criteria as currently set. [8.1.8]
- Major conclusions from the site inspections:
    - All water companies welcomed the discussions on this new technology

  - Water companies do not fully understand the requirement to issue satisfactory proposals to the DWI
  - There are different interpretations of 'compliance dates'.
  - It would have been premature to conduct Audits under Section 86 of the Water Industry Act 1991.
  - Log removal values are being used as alarm and shutdown settings
- Some water companies are retaining bypasses. Procedures and authorisation for using such need to be in-place.[7.4]
- It is suggested that the responses to the audited criteria can be classed under five categories. [7.3]
- Revising a PDT to identify a 1µm breach in hollow fibre membranes is feasible. [8.1.7, 8.1.8, 8.1.14]
- DWI should update the guidance note to suggest that, until water companies adopt compliant integrity tests and mathematically define the MIT frequency at the appropriate sensitivity, the practical MIT frequency is recommended to be daily.

Other additional conclusions and recommendations
The following are deemed important:

- DWI should consider single point of contact or a more structured approach to requests for *Cryptosporidium* information from water companies. [8.1.1]
- The progress if the ASTM protocol on membrane integrity testing should be kept under review. [4.4, 8.1.6]
- It is possible to monitor the product stream continuously for water quality parameters such as conductivity, particle count, colour etc., but this is not a direct MIT method and may not achieve the necessary sensitivity. [8.1.9]
- Future work should consider the membrane types not fully covered in this study, e.g. Degremont's Aquasource, AEA's Kerasep, etc. [8.1.3]
- DWI should encourage and support work to evaluate new membrane suppliers and monitoring techniques that are expected to become available and approved for *Cryptosporidium* removal duty in the future. [4.4]
- DWI should convene an internal 'closed' workshop to discuss the issues arising from this report.

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10 GLOSSARY

10.1 Terms

Array
A number of racks connected in parallel with common feed and treated main headers. In order to ensure security of supply during cleaning, backflushing or maintenance, an array may often include standby rack capacity. (e.g. 5 x 25 % or 11 x 10 % capacity racks)

Block
See Rack

Capillary Element
Hollow fibre membranes of small internal diameter (typically 0.5 to 1.5 mm) formed into a bundle, which may contain several thousand individual fibres. The fibres are normally sealed in epoxy blocks, which are then machined to provide open fibres at both ends. In situ cleaning methods including backflushing are possible.

Cartridge
See Module.

Cross Flow Filtration
Membrane separation process where the feed stream flows at a relatively high velocity parallel to the membrane surface in order to minimise the rate of accumulation of retained solids on the membrane surface. Despite this, retained particles accumulate on the surface forming a layer of solids, or filter cake so that resistance to fluid flow increases with operating time. Once either the flux declines, or the applied hydrostatic pressure increases to a predetermined value, then the membrane requires to be cleaned to remove the accumulated solids. Since a proportion of the feed stream passes through the membrane, the feed stream is divided into permeate and retentate streams. Cross flow filtration is typically used in ‘dirty’ service applications in the wastewater and industrial sectors.

Dead End Filtration
Membrane separation processes where the feed stream flows perpendicular to the membrane surface, and the feed and treated stream flowrates are identical. The retained particles accumulate on the surface forming a layer of solids, or filter cake so that resistance to fluid flow increases with operating time. Once either the flux declines, or the applied hydrostatic pressure increases to a predetermined value, then the membrane requires to be cleaned to remove the accumulated solids.

Direct Integrity Test
The membrane integrity is determined by measurement of the permeation properties of the membrane, typically by bubble point or diffusion tests.

Element
The membrane element comprises of a number of individual membrane fibres, or flat sheets engineered into a commercial package configuration. There are several basic types of element, which are used in water treatment: capillary; plate and frame; spiral wound; and tubular.

Flux
The flowrate of permeate through the membrane barrier per rack cross section of membrane area. Typically stated as litres/m^2/hour, often abbreviated to lmh.

Indirect Integrity test
The membrane integrity is determined by measurement of the separation properties of the membrane, typically by monitoring the passage of unwanted particles (often with a surrogate particle such as carbon, or a bacteria challenge test).

Log Removal Value or Log Reduction Value
This is defined in terms of an order of magnitude removal. For example a 4 log removal is equivalent to 99.99 % reduction in concentration of a particular particle size of the unwanted species

Membrane
A semi-permeable barrier, which is designed to achieve the required separation process. Membranes can be constructed from synthetic materials (typically polymers and elastomers), natural products (e.g. cellulose), or inorganic materials (e.g. ceramics or metals). Membranes are usually formed as either flat sheets, or hollow fibres, and are selected for optimum separation characteristics, mechanical and thermal stability, chemical resistance, and cost.

Membrane Integrity Test
A non-destructive test, which is used to verify the integrity of the membrane as a barrier.

Microfiltration
Filtration, or sieving, through a semi-porous membrane barrier under an applied hydrostatic pressure driving force, in the approximate size range 0.1 to 1.5 µm.

Module
The complete assembly of one vessel containing one or more membrane elements Some hollow fibre modules have integral elements and vessels; and are supplied as one component. Some manufacturers term the modules as cartridges.

Nanofiltration
Filtration of lower MW organics and polyvalent salts in the approximate size range 0.001 to 0.01 µm from a fluid through a semi-porous membrane barrier under an applied hydrostatic pressure driving force. The membrane osmotic pressure differential has to be considered due to the partial separation of dissolved species by the membrane.

Permeate
The stream passing through the membrane barrier.

Rack
A number of individual modules connected together in parallel with common feed, treated, and cleaning or backflushing piping manifolds. Sometimes called 'Unit' or 'Block'.

Retentate
The stream retained, or concentrated by the membrane barrier and hence only applicable with the cross flow filtration process.

Spiral Wound Element
A number of flat sheet membrane leaves are sandwiched and wound around a central, porous, permeate collection tube, with a feed channel spacer mesh separating individual leaves. Feed passes axially under cross flow filtration along the feed channel. Narrow feed channels (typically 1mm) mean that a high packing density can be used, but the element is more susceptible to particulate fouling. This design is not normally suitable for backflushing due to the low strength of the membrane leaves under reverse pressure.

Train
A membrane process 'train' or is a series of modules and processes, which makes up a complete treatment process. A membrane based water treatment works may have several parallel process trains, which can be operated independently if required.

Tubular Membrane Element
Hollow fibre type membranes of larger internal diameter (typically 1 to 2 cm) formed into a bundle, which may contain several individual tubes. Tubular membrane elements typically operate with turbulent cross flow filtration on ‘dirty’ feedwaters. In situ cleaning methods including backflushing and sponge ball cleaning are possible.

Ultrafiltration
Filtration, or sieving, through a semi-porous membrane barrier under an applied hydrostatic pressure driving force, of macromolecules and colloidal particles from a fluid in the approximate size range 0.01 to 0.1 µm. Osmotic effects are minimal.

Unit
Refer to Rack

Vessel
A membrane 'vessel' is a housing for the membrane elements. Typically, it consists of a cylinder with suitable end fittings, adaptors and connectors for the various piping connections. A vessel can contain more than one element. The complete assembly of one vessel containing one or more membrane elements is referred to as a module.

10.2 Abbreviations

ASTM	American Standards for Testing Materials
AWWA	American Water Works Association
AWWARF	American Water Works Association Research Foundation
Capex	Capital expenditure
CIMAH	Control of Industrial Major Accident Hazards
CMF	Continuous Microfiltration
COSHH	Control of Substances Hazardous to Health
CPP	Committee on Products and Processes
DAF	Diffusive Air Flow Test
DWI	Drinking Water Inspectorate
EDS	European Desalination Society
HACCP	Hazard Analysis and Critical Control Point (study)
HAZOP	Hazard and Operability (study)
IDA	International Desalination Association
IPPC	Integrated Pollution Prevention and Control (planning and/or procedures)
IPR	Intellectual Property Rights
IT	Integrity Test
IWA	International Water Association
JWWA	Japanese Water Works Association
LGC	Laboratory of the Government Chemist
LRV	Log Removal Value or Log Reduction Value
MF	Microfiltration
MI	Membrane Integrity

MIT	Membrane Integrity Testing
Mld	Megalitres per day
Opex	Operating expenditure
NF	Nanofiltration
PAC	Powdered Activated Carbon
PD	Pressure Decay
PDT	Pressure Decay Test
PFD	Process Flow Diagram
P&ID	Piping & Instrumentation Diagram
PHT	Pressure Hold Test
RO	Reverse Osmosis
RSC	Royal Society of Chemistry
SCADA	System Control and Data Acquisition
SIM™	Spiked Integrity Monitoring
TFC	Thin Film Composite
TOC	Total Organic Carbon
UF	Ultrafiltration
UV	Ultraviolet (radiation)

11 APPENDICES

Please refer to document, 'Final Report - Appendices'.

guardians of drinking water quality
DRINKING WATER INSPECTORATE

Review of the Adequacy of Existing Proposals for Membrane Integrity Monitoring

Final Report[1]- Appendices - Commercial in Confidence

Client: Drinking Water Inspectorate

DWI ref: 43/2/159

Issue: Final

Date: 31 October 2001

Initials:

Approved: C.Jackson - Deputy Chief Inspector

Signed:

Date:

1. This report and its conclusions, recommendations and suggestions are based on the assessment of a small selection of documents and information. Its conclusions are those of the authors. Any statements of satisfaction represent the Assessors' opinions at the time, based on the information available to them, and do not constitute a general endorsement of the adequacy of any Company's procedures or practices

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INDEX

F LITERATURE REVIEW

F.1 Method

The Nerac organisation in the United States was used as an expert Information Scientist to trawl international electronic databases against English key words, with a time limitation of current back to 1990. Nerac have been in business for 33 years and has access to worldwide resources, including those found on the Web, and its own scientific, technical, business and engineering databases. It retrieves strategic research, journal articles, patents, and standards that are pertinent.

This first search produced a list of abstracts that the team then reviewed, selecting the most appropriate papers for retrieval.

Retrieved papers were then reviewed to reduce final numbers, with the most appropriate ones entered into the project literature database. Papers from other sources (e.g. in-house, membrane companies, water companies) were also included where appropriate. The full list of papers remaining after the initial screening can be found in Appendix F.4. This database also describes whether or not we hold a hard copy of a paper.

Copies of the papers were obtained from both internal and external sources. The papers for which we held copies were considered sufficient for the purposes of this study and were further reviewed as described below.

In addition to this review, information pertinent to this study was obtained from other sources. A summary of these findings is given in Section F.3.

F.2 Review

The basis for the literature review has already been described. The review enables useful information regarding membrane integrity testing concepts and operational histories from around the world to be described.

There are various methods to assess the reliability of UF and MF systems using both direct and indirect methods. The PDT has been reported to be the most effective direct method [1,4] although this method is not continuous and is limited to a test every 6 hours[3]. A suitable method for continuous integrity monitoring relies on particle counting [1,4] although such monitoring would be expensive for large-scale plant.

Studies to evaluate various methods of assessing the integrity of RO systems for microbial removal have suggested [2,4] that the vacuum test (direct) is useful as a screening procedure to test RO membrane elements prior to installation into the system. Random sampling[8] can be adopted for a large quantity of membranes. On-line conductivity monitoring, conductivity probing and microbial seeding were useful methods to evaluate system integrity. Kruithof[8] comments that sulphate monitoring is another technique that can be used.

The indirect method of particle counting (>1µm) is not a sensitive enough method to monitor the integrity of the RO system[2,6]. Panglisch builds on work by others and reports[10] a relationship between the number of particle counters required and feed water particle concentration, type of membrane, plant size. A system has recently been developed to dose powdered activated carbon into the feed and it is reported[8,12] that the system provides increased sensitivity by increasing the feed water particle concentration. Testing to develop a reliable and robust on line integrity test for a broad range of log removals is continuing[8]. More than one method may be necessary to ensure reliable operation of the RO system[2]

The direct methods of pressure decay or diffusive airflow are considered simple and reliable ways of monitoring membrane integrity during operation. These tests can be automatically controlled with logging of data and automatic shutdown of the part of the system that has failed the test. Work to directly relate these results to microbial removal continues [5,6] and should be followed-up in future DWI study work. Laîne has reported[9] that acoustic sensors can be employed to continuously assess membrane integrity; their viability is limited by background noise and flux rate. It seems to be a promising technique that again which should be followed should be followed-up in future DWI study work

Banerjee[3] has recently found that laser turbidimeters are a useful instrument to indirectly measure membrane integrity. However, like particle counters, they are not able to assess loss of integrity for a large system of membrane elements. His study did note that both particle counters and laser turbidimeters can recognize a backwash event and that, in the event of an integrity problem, the backwash events are amplified well in excess of the increase in the baseline operation value for both laser turbidity and particle counting. Further study of this significant observation will take place by Banerjee and should be followed-up in future DWI study work.

Trimboli[11] describes the implementation of a bacillus spore challenge test to measure the integrity of a large membrane system. The test is sensitive though expensive for a large facility. However, the work also suggested that USF Memcor direct integrity test methods, e.g. PDT and DAF tests, underestimated spore rejection. This confirms Johnson's suggestion[6] that both these tests are conservative.

There appears to be little long-term data on the subject of continuous monitoring of membranes able to remove particles greater than 1µm product water quality and operational and maintenance requirements. However, Kothari[7] stresses that a water provider should note the importance of strong performance guarantees and/or conservative interpretation of pilot results when planning new facilities. He also notes that the regulatory agency's criteria for demonstrating membrane integrity can increase the plant's operating costs. However, he does not suggest any alternatives. It is hoped that that future work by others and the audit/ discussions of plant in this study will both further illuminate the issue.

1. Adham, S. et al, *Low-pressure membranes: assessing integrity*, AWWA Journal, Vol. 87 #3, 1995

2.Adham, S. et al, *Monitoring the integrity of reverse osmosis membranes,* Desalination 119 (1998) 143-150

3. Banerjee, A. et al, *Membrane integrity using high sensitivity laser turbidity*, Proceedings of the conference on membranes in drinking and industrial water production, Volume 2, pp191-194, 2000

4. Gagliardo, P. et al, Development of an innovative technique to evaluate the integrity of an integrated membrane system applied for water repurification, IDA San Diego conference proceedings, Vol. 1, pp 227-238

5. Hong, S. et al, *Removal of microorganisms by MF process: correlation between membrane integrity test results and microbial removal efficiency*, AWWA Membrane Technology Conference, Long Beach, 1999

6. Johnson, W., *Predicting log removal performance of membrane systems using in-situ integrity testing*, AWWA Membrane Conference Proceedings, Vol. A, 1997

7. Kothari, N. et al, *Microfiltration case study - lessons learned during implementation of a 14.5 MGD plant*, Conference on Membranes in Drinking and Industrial Water Production, Paris, 3-6 October 2000.

8. Kruithof, J. et al, *Development of a membrane integrity monitoring strategy for the RO/UF Heemskerk drinking water,* Conference on Membranes in Drinking and Industrial Water Production, Paris, 3-6 October 2000.

9. Laîne, J.-M., *Acoustic sensor: a novel technique for low pressure membrane integrity monitoring*, Conference on Membranes in Drinking and Industrial Water Production, Amsterdam, 21-24 September 1998.

10. Panglisch, S. et al, *Monitoring the integrity of capillary membranes by particle counters*, Conference on Membranes in Drinking and Industrial Water Production, Amsterdam, 21-24 September 1998.

11. Trimboli, P. et al, *Demonstrating the integrity of a large-scale microfiltration plant using a bacillus spore challenge test*, Conference on Membranes in Drinking and Industrial Water Production, Paris, 3-6 October 2000.

12. Van Hoof, S.C.J.M. et al, *Development of a new on-line membrane integrity testing system*, AWWA Membrane Technology Conference, San Antonio, March 2001

F.3 Other findings

F.3.1 American Water Works Association Research Foundation (AWWARF)

A parallel two-year study into the subject of MIT has been initiated by AWWARF. It had been the hoped that some areas of common cause might have been described in this report. However, the AWWARF work has not yet progressed sufficiently. Perhaps, future study can address this issue.

F.3.2 American Standards for Testing Materials (ASTM)

In the US, ASTM Task Group D19.08.02 has recently (9 April 2001) issued a draft for review entitled, *Standard Practice for Integrity Testing of Membrane Systems*. The standard codifies some of the test methods that have already been described in this report. It is anticipated that this draft, incorporating modifications, will be adopted in early 2002. Some important findings are described in the draft and are repeated here.

"This practice covers the determination of the integrity of membrane elements and systems using air based tests (pressure decay and vacuum hold), soluble dye, and TOC monitoring tests. The tests are applicable to systems with membranes that have a nominal pore size less than about 1 µm. The TOC and Dye tests are generally applicable to NF and RO only.

……………The integrity test methods described are used to monitor the integrity of membrane systems, and are applicable to systems containing membrane module configurations of both hollow fiber and flat sheet – such as spiral-wound configuration. In all cases the practices apply to membranes in the reverse osmosis (RO), nanofiltration (NF), and ultrafiltration (UF) membrane categories. However, the TOC and Dye Test practices do not apply to membranes in the microfiltration range or the upper end of the UF pore size range (0.01µm and larger pore sizes) due to insignificant or inconsistent removal of TOC material by these membranes.

These methods are used to identify relative changes in the integrity of a system, and may be correlated with actual log reduction values by experiment for the particular membrane and system configuration used.

The ability of the methods to detect any given defect is affected by the size of the system tested. Selecting smaller portions of the system to test will increase the response of the test to defects. When determining the size that can be tested as a discrete unit, use the guidelines supplied by the system manufacturer or the general guidelines provided in this standard.

The applicability of the tests is largely independent of system size when measured in terms of the impact of defects on the treated water quality (i.e the system LRV). This is because the bypass flow from any given defect is diluted in proportion to the permeate flowrate. For example, a 10-module system with a single defect will produce the same LRV as a 100-module system with ten of the same size defects.

……………….RO and NF permeate is often too pure to monitor particles, turbidity or even conductivity. When there is a small leak it is diluted over the system such that conductivity changes will be within normal variability. Also, conductivity could increase because of differences in the feed solution or the membrane that do not indicate a breach of integrity. Since RO and NF membranes retain dissolved organics at a higher rate than dissolved salts, TOC monitors may be able to detect leaks that may correspond to breeches in integrity."

F.4 Literature Database

Author	Title	Where presented	Copy of paper	Date presented	Sponsoring organisation	Literature reference
	Monitoring the integrity of reverse osmosis membrane systems in a wastewater recycling project	Innovator's Digest	No	01/01/00		2000/23/11-14
Adham, S. Gagliardo, P.; Smith, D.; Ross, D.; Gramith, K.; Trussell, R.	Monitoring the integrity of reverse osmosis membranes	Amsterdam	Yes	26/09/98		pp 143-150
Adham, S.; Gagliardo, P.; Gramith, K.	Environmental technology verification program of various ultrafiltration systems	Paris	Yes	01/10/00	IWA, EDS, AWWA, JWWA	
Adham, S.; Jacangelo, J.; Laine, J.-M.	Low -Pressure Membranes: Assessing Integrity	Denver	Yes	01/03/95	AWWA	Journal AWWA, 87(3):62-75
Anselme, C.; Jacobs, E.P.	Ultrafiltration in Water Treatment Membrane Processes		No	01/01/96	AWWARF, Lyonnaise des Eaux, Water Research Commission of South Africa	
Banerjee, A.; Carlson, K.; Marinelli, F.; DeNatale, K.	Monitoring Membrane Integrity with Laser Turbidity	Denver	No	01/01/00	AWWA	Proc. of the 2000 AWWA Annual Conference
Banerjee, A.; Lambertson, M.; Lozier, J.; Colvin, C.	Monitoring membrane integrity using high sensitivity laser turbidimetry	Paris	Yes	01/10/00	IWA, EDS, AWWA, JWWA	

Author	Title	Where presented	Copy of paper	Date presented	Sponsoring organisation	Literature reference
Bou-Hamad, S.	Performance restoration and autopsy of microfiltration membranes	Paris	Yes	01/10/00	IWA, EDS, AWWA, JWWA	
Dahmann, P.; Mager, M; and Gossen, F.	Inevitable Inaccuracy of Particle Counting and the Influence on Hydraulic Filter Testing	Filtech	Yes	01/01/93	Filtech	
Drage, B.; Upton, J.; Holden, P; Marchant, J.	River Trent on tap - comparison of conventional and membrane treatment processes	Lancaster	Yes	01/03/00	RSC	
Dwyer, P.; Collins, R.; Margolin, A.; Hogan, S.	Assessment of Bacteriophage, Giardia Cysts, Cryptosporidium Oocysts and Organic Carbon Removals by HF Ultrafiltration	Reno, Nevada	Yes	01/08/95	AWWARF	
Edwards, D.; Bruce, B.; Donn, A.; Meadowcroft, C.	Control of Cryptosporidium risk in groundwater sources	Paris	Yes	01/10/00	IWA, EDS, AWWA, JAWA	
Franklin, B.; Smith, R.; Knops, F.	Using Membranes as a Cryptosporidium Barrier for the World's Largest Municipal Ultrafiltration Plant	Denver	No	01/01/00	AWWA	Proc. of the 2000 AWWA Annual Conference
Galiardo, P.; Chambers, Y.; Adham, S.; Trussell, R.	Development of an innovative technique to evaluate the intergity of an integrated membrane systemj applied for water repurification	San Diego	Yes	01/09/99	IDA	IDA 1072
Glucina, K.; Do-Quang, Z.; Laine, J. M.	Assessment of a particle counting method for hollow fiber membrane integrity	Desalination	No	01/01/97		113/2-3/pp183-187

Author	Title	Where presented	Copy of paper	Date presented	Sponsoring organisation	Literature reference
Glucina, K.; Laine, J.-M.; Anselme, C.; Chamant, M.; Simonie, P.	Acoustic Sensor: a novel technique for low pressure membrane integrity monitoring	Long Beach	No	01/01/99	AWWA	Proc. of the 1999 AWWA Membrane Technology Conference
Gregory, J.	Cryptosporidium in Water: Treatment and Monitoring Methods	Water Filtration Processes, G-Mex Centre, UK	Yes	09/02/94	Water Filtration Processes	
Hach Company	Preliminary product information, Introducing Medusa: an online, multi-sensor, membrane filtration monitoring system		No	01/01/00		
Hong, S.K.; Taylor, J.S.; Miller, F.; Rose, J.; Gibbson, C.; Owen, C.; Johnson, W.	Removal of microorganisms by MF process: correlation between membrane integrity test results and microbrial removal efficiency	Long Beach	Yes	28/02/99	AWWA	Proc. of the 1999 AWWA Membrane Technology Conference
Jacangelo, J.	Removal of cryptosporidium parvum, giardia muris, and MS2 bacteriophage by hollow fibre microfiltration and ultrafiltration		Yes		AWWA	
Jacangelo, J.; Adham, S.; Laine, J.-M.	Membrane Filtration for Microbial Removal	Denver	No	01/01/97	AWWARF and AWWA	AWWARF/DWI proposal
Jacangelo, J.; Aieta, M.; Carns, K.; Cummings, E.; Mallevialle, J.	Assessing HF Ultrafiltration for Particle Removal	AWWA	Yes	01/01/89		Journal AWWA November 1989

Author	Title	Where presented	Copy of paper	Date presented	Sponsoring organisation	Literature reference
Johnson, W. T	Automatic monitoring of membrane integrity in microfiltration systems.	Desalination	No	01/01/97		113/2-3/pp303-307
Johnson, W. T	Predicting log removal performance of membrane systems using in-situ integrity testing.	Filtration and Separation	Yes	01/02/98		35/1/pp26-29
Johnson, W.; Patterson, A.	Application of a new generation microfiltration process for large scale water and wastewater treatment	Lancaster	Yes	01/03/00	RSC	
Kamp, P.; Kruithof, J.; Folmer, H.	UF/RO treatment plant Heemskerk: from challenge to full scale application	Paris	Yes	01/10/00	IWA, EDS, AWWA, JWWA	
Kim, P.; Kartinen, E.Jnr.; Martin, C.	Developong a protocol for rapid health department certification of membrane filtration systems	Long Beach	No	01/01/99	AWWA	Proc. of the 1999 AWWA Membrane Technology Conference
Knops, F.; Franklin, B.	Ultrafiltration for 90 MLD Cryptosporidium and Giardia free drinking water: a case study for the Yorkshire Water Keldgate Plant	Paris	Yes	01/10/00	IWA, EDS, AWWA, JAWA	
Kothari, N.; Schideman, L.; Brown, D.	Microfiltration case study - lessons learned during implementation of a 14.5 MGD plant	Paris	Yes	01/10/00	IWA, EDS, AWWA, JWWA	
Kruithof, J.; Kamp, P.; Folmer, H.	The first full-scale ultrafiltration/ reverse osmosis plant in the Netherlands in operation	Denver	No	01/01/00	AWWA	Proc. of the 2000 AWWA Annual Conference

Author	Title	Where presented	Copy of paper	Date presented	Sponsoring organisation	Literature reference
Kruithof. J.; Kamp, P.; Folmer, H.; Nederlof, M.; van Hoof, S.	Development of a membrane integrity monitoring strategy for the UF/RO Heemskerk drinking water treatment plant	Paris	Yes	01/10/00	IWA, EDS, AWWA, JWWA	Proceeding Vol 2 pp 173-184
Laine, J. M.; Glucina, K.; Chamant, M.; Simonie, P	Acoustic sensor: A novel technique for low pressure membrane integrity monitoring	Amsterdam	Yes	26/09/98		pp 73-77
Liu, C.; Fushijama, M.; Hayes, J.; Moy, J.	Finding a needle in a haystack: integrity test of membrane filters in drinking water applications		Yes	01/10/99	AWWA	
MacCormick, T; Trimboli, P; Petrenas, B; and Speir, J.	The 36 Ml/d MF WTP at Tauranga Achieves Cryptosporidium and Giardia Compliance		Yes	01/01/98		
Memtec	Membrane integrity monitoring in large scale systems		Yes			Membrane Technology No. 95
Nash, C.; Stewart, J.; Muntisov, M.	Combining microfiltration, ozone,and BAC - the Trentham experience	Paris	Yes	01/10/00	IWA, EDS, AWWA, JWWA	
Panglisch, S.; Deinert, U.; Dautzenberg, W.; Kiepke, O.; Gimbel, R.	Monitoring the integrity of capillary membranes by particle counters	Amsterdam	Yes	26/09/98		pp 65-72
Trimboli, Peter; Lozier, Jim; Johnson, Warren	Demonstrating the integrity of a large-scale microfiltration plant using a bacillus spore challenge test	Paris	Yes	01/10/00	IWA, EDS, AWWA, JWWA	
van Hoof, S.C.J.M.; Kruithof, Joop C.; Kamp, Peer C.	Development of a new on-line membrane integrity testing system	San Antonio	Yes	01/03/01	AWWA	

Author	Title	Where presented	Copy of paper	Date presented	Sponsoring organisation	Literature reference
Wale, R.T.; Vickers; J.C., Page, G.J	Potable water and wastewater treatment		Yes			
Wilf, M.; Alt, S.	Reduction of Membrane Fouling and Improving Elements Integrity in Municipal Wastewater Reclamation	San Diego	Yes	01/09/99	IDA	IDA 1154

G EXTRACT FROM DWI INFORMATION LETTER 16/99 OF 20/12/00

Background

The Guidance on Assessing Risk from *Cryptosporidium* Oocysts in Treated Water Supplies ("the Guidance") associated with the Water Supply (Water Quality) (Amendment) Regulations 1999 ("the 1999 Regulations") includes the following:

*"**2. Risk Assessment***

1.1 Water companies must carry out a risk assessment for each of their water treatment works taking into account the factors listed in Annex A. However, for the purposes of the Regulations, the Secretary of State considers that the following water treatment works should in all cases (other than 2.2 below) be classified as constituting a significant risk.

Direct abstraction or with average storage of seven days or less from a river or stream.

Evidence of rapid river or surface water connection to the aquifer demonstrated by the confirmed presence of faecal coliform bacteria in the raw water.

Past history of an outbreak of cryptosporidiosis associated with the water supply where the reason is unexplained and no specific steps have been taken to prevent a recurrence.

2.2. Any treatment works, in which all water passes through sufficient treatment plant capable of continuously removing or retaining particles greater than one micron diameter and where this process is subject to continuous monitoring and shutdown or turn out on failure, will not require continuous monitoring irrespective of other factors, including 2.1 (i), (ii) and (iii) above."

3. Some companies are considering the use of membrane and other filtration systems to meet the requirement of paragraph 2.2 above and thereby avoid the requirement under the 1999 Regulations to install continuous sampling equipment.

4. A number of membrane and other filtration systems have been approved under regulation 25 of the Water Supply (Water Quality) Regulations 1989 ("the 1989 Regulations") and these are listed in section 7 of the Secretary of State's List of Approved Products. The Committee, which advises the Secretary of State on approvals, considers whether the use of a product will cause a risk to the health of consumers. The Committee does not consider fitness for purpose and listing of an approved product does not constitute an endorsement of the claims of manufacturers/suppliers.

5. It is for water companies to decide which membrane or other filtration systems to use so as to meet the requirement of the 1999 Regulations that the water entering supply from their treatment works contains an average of less than one *Cryptosporidium* oocyst per 10 litres of water. Of course, any system used must be

approved under regulation 25 of the 1989 Regulations. However, if the membrane or other filtration system does not comply with paragraph 2.2 above, continuous sampling and daily analysis under the 1999 Regulations will be required.

6. In order to assess claims by water companies that they do not need to install continuous sampling equipment to monitor the effectiveness of the treatment process under the 1999 Regulations because they had installed, or were planning to install, treatment capable of removing or retaining particles greater than one micron diameter, the Inspectorate considered that it was necessary to have an independent assessment of the claims of manufacturers/suppliers in respect of the ability of their products to remove particles.

7. The Inspectorate commissioned the Laboratory of the Government Chemist (LGC) to carry out the review. LGC was asked to assess whether manufacturers/suppliers holding approvals for membranes and other filtration systems had provided evidence that their products were capable of removing or retaining particles with a diameter of greater than one µm. The LGC report cannot be made publicly available because some of the information provided by the manufacturers/suppliers is commercially confidential.

8. A number of manufacturers/suppliers have not made specific claims for removal of *Cryptosporidium*, or for removal of particles of a specific size. It was necessary therefore for LGC to consider whether the test data that had been submitted was adequate for the purposes of this review. LGC were asked to pay particular attention to whether the testing had been sufficiently rigorous, given the particular difficulties in performing *Cryptosporidium* removal studies at concentrations encountered in the environment. In reviewing the information provided by manufacturers/suppliers, LGC considered:

(a) whether data from testing for removal of particles other than *Cryptosporidium* was relevant to this assessment;
(b) whether membrane reliability had been addressed;
(c) whether worse case scenarios had been taken into account; and
(d) whether experimental test design, including control experiments, was satisfactory.

9. In respect of 8(a) above the following test data were considered to provide satisfactory evidence for removal or retention of particles with a diameter of greater than one µm:

- chloride ion or hardness ion rejection; or
- removal of all *Cryptosporidium* oocysts; or
- removal of bacteria, bacterial spores, bacteriophages or viruses.

In the future it is possible that other types of test data may also provide satisfactory evidence of one µm particle removal.

List of products capable of removing or retaining particles greater than one µm diameter

10. The Inspectorate has assessed the LGC report. The Inspectorate considers that on the basis of the evidence provided, the following manufacturers/suppliers have shown that the listed products, all of which have been approved under regulation 25 of the 1989 Regulations, are capable of removing or retaining particles with a diameter of greater than one µm.

Company	**Product**
AEA Technology Ltd	Kerasep Cross Flow Filtration Module
Fluid Systems Ltd	TFC Membrane Elements
Degremont UK Ltd	Aquasource UF Membrane Module
Kalsep Ltd Element	Kalmem Polyethersulphone Hollow Fibre
Koch Membrane Systems Ltd	Targa Modules V and H
US Filters Ltd M1/M2 and M10	CMF Continuous Microfiltration Systems
PCI Membrane Systems Ltd Element	PCI Membrane Filtration System – Spiral PCI B1 Module and Membrane – Tubular Element 1 PCI Tubular C10 Module and Membrane System (incorporating Tubular Element 1)
X Flow BV	X Flow Membrane Filtration Elements

11. Products have not been included in the list in paragraph 10 above where claims from manufacturers/suppliers for removal of particles have been based on:

(a) the physical characteristics of the material and the integrity of the manufacturing process; or
(b) limited test data or inadequate experimental design; or
(c) evidence that particles of a diameter of one µm or greater are not completely removed.

Any manufacturers/suppliers whose approved products have not been included in the list in paragraph 10 on these grounds may ask the Inspectorate for a review of their product if they submit additional relevant testing data. Any manufacturers/suppliers whose products have not been approved under regulation 25 of the 1989 Regulations will need to obtain such approval before the Inspectorate will consider test data for the removal of particles. The list in paragraph 10 will be up-dated when existing and new approved products have been demonstrated to the satisfaction of the Inspectorate to remove or retain particles greater than one µm diameter.

Integrity of membrane or other filtration systems

12. Paragraph 2.2 above of the Guidance requires the treatment process to be subject to continuous monitoring and shutdown or turn out on failure if it is to be used to avoid the requirement for continuous sampling under the 1999 Regulations. It follows that manufacturers/suppliers must include with their membrane or other filtration systems a system of monitoring to detect whether there is a failure of integrity of the filter barrier. Any significant failure of integrity must lead to cessation of supply of the affected water from the treatment works. In modular filtration systems it may be acceptable to remove just the failed module from supply provided there is a system for identifying accurately any failed module.

13. As design of membrane and other filtration systems varies widely between different manufacturers and suppliers, the Inspectorate is not able to give detailed advice on integrity testing. The Inspectorate understands that systems based on bubble tests under pressure or vacuum and systems based on challenge by inert particles and monitoring turbidity or particle count/size may be suitable. Ideally there should be continuous monitoring of integrity using these techniques but the Inspectorate recognises that this may not be practical for some techniques. Intermittent monitoring at an appropriate frequency based on system design and risk of failure may be acceptable. Other options that water companies or manufacturers/suppliers wish to put forward would be considered by the Inspectorate (see paragraph 14 below). Where automated monitoring systems are installed, these should be linked to a control room by telemetry with appropriate alarms when failure of integrity of the filter barrier occurs.

14. Water companies proposing to install membrane or other filtration systems to avoid continuous sampling under the 1999 Regulations should ask the manufacturers/suppliers to provide full details of their system of monitoring the integrity of the filtration system and make an assessment of whether that is adequate for the system design and the circumstances at the treatment works. Water companies are required to include in their submission to the Inspectorate on the programme for implementation of regulation 23(B)(1) of the 1999 Regulations, details of the system to be used for monitoring the integrity of the membrane or other filtration systems that they propose to install.

H GUIDANCE ON SUBMISSIONS OF CLAIMS FOR REMOVAL OF ONE MICRON PARTICLES - MEMBRANE TREATMENT PROCESSES FOR *CRYPTOSPORIDIUM* REMOVAL

GUIDANCE ON SUBMISSIONS OF CLAIMS FOR REMOVAL OF ONE MICRON PARTICLES - MEMBRANE TREATMENT PROCESSES FOR *CRYPTOSPORIDIUM* REMOVAL

Background

1. *Guidance on Assessing Risk from Cryptosporidium Oocysts in Treated Water Supplies* has been developed by the Drinking Water Inspectorate (DWI) to support *The Water Supply (Water Quality) (Amendment) Regulations 1999* (Statutory Instrument 1524). The provisions of the 1999 regulations have now been incorporated in to the Water Supply (Water Quality) Regulations 2000. Copies of the Guidance and the Regulations are posted on the DWI website: http://www.dwi.detr.gov.uk/regs/index.htm

2. Section 2.2 of the Guidance provides that 'any treatment works, in which all water passes through sufficient treatment plant capable of continuously removing or retaining particles greater than one micron diameter and where this process is subject to continuous monitoring and shutdown or turn out on failure, will not require continuous monitoring'.

3. This report contains guidance on the information to be provided by membrane suppliers in support of an application to DWI for listing of products as satisfying the criterion for removal of Cryptosporidium. Product information is not eligible for consideration unless the product is included in *List of Products and Processes Approved Under Regulations 25 and 26 For Use In Connection With The Supply Of Water For Drinking, Washing, Cooking And Food Production Purposes.* A copy of the List of Approved Products and updates to the list are posted on the DWI website: http://www.dwi.detr.gov.uk/soslist/index.htm

4. The assessment criterion is that products must be capable of continuous removal (or retention) of particles of one micron diameter and greater from a representative feed water. The report deals only with size exclusion. Advice on membrane integrity issues and systems for monitoring membrane integrity are the subject of a DWI Information Letter [XXX]. DWI will ensure that assessments are made independently of the commercial interests of manufacturers and suppliers of membrane and other filtration systems.

Requests for assessment – initial submission

5. Requests for an assessment of product data should be addressed to Anthony Lloyd, tel: 020 7944 8037, E-mail anthony.lloyd@defra.gsi.gov.uk. There are no specific requirements for format of submissions for assessment but suppliers must include:

- Contact details, including e-mail address, of the lead contact appointed by the supplier to co-ordinate the submission, and to deal with any correspondence over the assessment.

- A clear description and identification of the product to be assessed. This identification must appear on all parts of the information provided, to prevent ambiguity.

- Copies of claims made for the product that are relevant to the assessment.

- Relevant evidence about product performance in the water treatment process and the permitted operating conditions for the product when it is used in processes for drinking water treatment.

Test data in support of submissions

6. DWI Information Letter 16/99 advised that test data on removal of oocysts of *Cryptosporidium* must indicate removal of all oocysts. In this respect, Cryptosporidium challenge tests are unlikely to provide definitive evidence of compliance with the assessment criterion. This follows from the limitations in the reproducibility and detection limit of available analytical techniques. However, suppliers may wish to provide results of Cryptosporidium challenge tests as supporting evidence.

7. Removal data on a range of alternative particles may be submitted as evidence for compliance with the test criterion e.g. bacteria, bacterial spores, viruses, phage particles and dissolved molecules or ions. The assessment will take account of possible differences in behaviour and size of the substitute particles and suppliers should provide a justification of why the behaviour of a particular particle is an adequate substitute for Cryptosporidium.

8. Similarly, particle removal tests are unlikely to provide definitive evidence of compliance with the assessment criterion, because of the uncertainties associated with ensuring zero breakthrough. However, suppliers may again wish to provide results of particle removal tests as supporting evidence. Tests performed with particles having a maximum diameter greater than one micron will be of limited value for the purposes of the assessment.

9. Imaging techniques such as electron micrography focus on the product rather than the process. The modal pore size of a membrane or filter may readily be estimated in this way. Evidence that the pores are generally of less than one micron in diameter is valuable confirmation of particle removal studies. However, by itself, evidence about the topography of the product is insufficient for a definitive assessment because (i) it addresses the assessment criterion indirectly, (ii) individual pores may be very much larger than the modal size, and (iii) parts of the filter surface may exhibit anomalous characteristics.

10. Gas or liquid permeation tests and mechanical resistance tests may be submitted as corroborating evidence. By themselves, they are insufficient because they are indirectly related to the particle removal process. The test principles and calculations used should be fully detailed.

Guidelines for experimental design

11. It is recommended that product performance tests be specifically designed to evaluate compliance with the assessment criterion. If the tests were carried out with other applications in mind, this must be clearly stated in the description of the testing. Standard methods should be used wherever they are available and appropriate to the particles under consideration.

12. Test data may be obtained from experimental trials on production models or by monitoring the performance of working installations. Data from both types of studies will be advantageous. Data from working installations are particularly useful because they provide information on seasonal or episodic environmental variation, and human error. A complete operational record will generally be required.

13. Customer applications tests and product quality control tests may be submitted. The reason for carrying out such tests must be stated and the detailed procedure must be provided. Independent academic studies may provide comparative data on related products, but the provider's key contact must ensure that the product under assessment is clearly defined.

14. The results of tests carried out during product development are not eligible for consideration. Data must be obtained with identifiable products of known specification, using the commercial product under assessment. If it is necessary to use only a part of the commercial product for a particular test, or to study the commercial product integrated with other processes, this must be clearly stated at the head of each such test or study.

15. The Inspectorate will not consider tests results obtained in studies where two or more products are used in series. If it is necessary for water processed by the first unit to be treated by a second unit, then the product is not capable of complete removal of particles of the tested size and can not be assessed as meeting the assessment criterion.

16. The following points should be considered when designing performance tests:

- It will be necessary to reflect operational conditions thoroughly.

- Allowance must also be made for the recoveries, detection limits and linearity of analytical enumeration procedures, with appropriate control experiments.

- Results should be obtained for any start-up phase, shutdown phase or fluctuations during which water production might be allowed to continue, as well as for the steady state. This is particularly important if the retained material contributes to the filtration mechanism.

- It is desirable to include a control experiment for any dead volume contribution from, or adsorption to, apparatus that does not form part of the commercial product. Experiments in which the test apparatus is run without a barrier element in place are suitable

- A control experiment for adsorption to the barrier element of the commercial product would also be valuable. Adsorption may be allowed to occur for an extended interval in static mode (i.e. at zero flow rate) to determine whether it is a significant mechanism in particle removal.

Reporting

17. Test reports on product performance in the water treatment process should include the following:

- Scientific procedures. Published scientific procedures should be submitted with the test data or referenced, and any modifications should be detailed. Other scientific procedures should be submitted in full, either as part of or with documents containing the test data.
- Raw data. Generally, all raw data will be required. However, if the volume of raw data exceeds ten pages, contact DWI for advice on the submission format.
- Interpretation, calculations and the conclusions drawn. Experimental design and statistical procedures may be referenced. Additionally, a rationale for the experimental design is valuable. DWI may commission statistical advice to assess the level of confidence in the reported data.

18. DWI will seek to identify whether the experimental basis for the submitted data is sufficiently rigorous. The information submitted should therefore cover the following details:

- Characterisation of particle size, type and number introduced to the process.
- Procedure for introducing particles before the process.
- Operational conditions covered.
- Procedure for recovering particles after the process.
- Enumeration of the recovered particles.
- Replication of all stages.
- Allocation of personnel, checking of results and quality assurance.
- Any operational difficulties. It may be necessary to repeat or redesign the tests if substantial difficulties are encountered.
- Any points at which parts of the product were replaced or modified.
- Whether the effects of backwashing, cleaning or maintenance were tested.

The information available from in-process operational records may be less complete, but the same categories of information need to be addressed.

Assessment process

19. DWI will examine and critically evaluate the information received against the assessment criterion, having regard to the relative significance of different types of information for this purpose. DWI will provide a written opinion as to whether or not the product meets the assessment criterion. Products receiving a favourable assessment will be included in the list "Approval of membrane and other filtration systems for *Cryptosporidium* removal". This list is posted on the DWI website: http://www.dwi.detr.gov.uk/soslist/approval.htm

Conditions of listing

21. Listing is subject to the standard conditions of approval for all approved products in respect of: use in accordance with agreed Instructions for Use and approval of all changes to the product. Evidence about one product may be relevant to the assessment of a related product. For example, if the only intended difference is capacity. Nevertheless, the products should be clearly distinguished for the assessment. DWI will consider whether and to what extent cross-corroboration is appropriate.

These conditions of approval are as follows:

That use is in accordance with an Instructions for Use document. Approval holders must provide water companies with copies of the Instructions for Use Document that was considered by the Committee[1] *when approval was recommended.*

That the approval of the Authorities[2] *is obtained in respect of the following: any change in the formulation of the approved product, including change in source or identity of raw materials; any change in the manufacturing process, including location of manufacture; any change in designation of the approved product; and any change in name or ownership of the organisation holding the approval.*

1 The Committee on Products and Processes for Use in Public Water Supplies
2 The Secretary of State for Environment, Food and Rural Affairs and the National Assembly for Wales.