



Medicines & Healthcare products
Regulatory Agency

Responding to requests from Coroners and the Police (BRE 004-04)

Accountable Director:

[REDACTED] Chief Safety Officer, Safety
and Surveillance

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Revision History

This table sets out the revision history for the last three versions.

Version No.	Effective date	Author's Title	Change
1	17/01/2024	██████████ BRE Assessor	First published version for BRE
2	10/07/2024	██████████ BRE Assessor	Correcting links in 6.1.2.3, 6.4.2 and 6.8.2 following Sharepoint folder reorganisation
3	28/04/2025	██████████ BRE Head of TAU4	Sign off process of Reg 28 responses.
4	27/07/2026	██████████ BRE Assessor	Addition of Regulation 29 template for responses to Regulation 28 requests (6.8.1)

Consultation

Who	Date
Benefit risk assessors who have been involved in Coroner/Police investigations	Q3 2023-Q1 2024
PSM signal assessors involved in processing of reports	Q3 2023
BRE SMT	Q4 2023

Approval

Approval Path	Date
BRE SMT	16/01/2024
BRE SMT, [REDACTED] (2025 update)	April 2025

Replaces

(Archived) Devices Division: Coroner and Police requests: preparing and issuing a report or response (v1.8)

(Archived) VRM030_04 Handling Coroners Regulation 28 reports to Prevent Future Deaths (PFDs) and requests to appear as a witness or provide evidence to an inquest in the Vigilance and Risk Management of Medicines (VRMM) Division (v.4)

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1 Introduction

- 1.1 Coroners are independent judicial office holders. They are a type of specialist judge who investigates and explains certain kinds of deaths. The coroner's role is to find out who died and how, when, and where they died.
- 1.2 The coroner's investigation may include an inquest hearing. An inquest is a public court hearing held by the coroner to decide who died and how, when and where the death happened. It may be held with or without a jury, depending on the circumstances. At the inquest the coroner will hear from witnesses and consider other evidence such as post-mortem or expert reports. Not all deaths which are investigated by a coroner need to have an inquest.
- 1.3 An inquest is different from other types of court hearing because there is no prosecution or defence and only the coroner can decide what evidence to hear. As the purpose of the inquest is only to discover the facts of the death the coroner (or jury) cannot find anyone criminally responsible for the death. Please see ["Guide to coroner services"](#) from the Ministry of Justice for further details.
- 1.4 Where a medicine or medical device is implicated in a death, the coroner may request a formal report from MHRA on our investigation of the incident, and may require presentation of the evidence as a witness at the inquest. For events involving a medicine these are known as professional witness statements, and for events involving medical devices, they are known as pre-inquest summary letters.
- 1.5 A request may also be received from the Police for assistance with their enquiries.
- 1.6 When an Inquest reveals a risk of future fatalities, the coroner must report the circumstances of the death to those who might be able to take action to prevent future deaths (Regulation 28 report, also known as a Prevention of Future Deaths Report). An explanation of the nature of a Regulation 28 request can be found on the [Courts and Tribunals Judiciary website](#).
- 1.7 This procedure outlines the handling and drafting of witness statements, pre-inquest summary letters and responses to regulation 28 reports, and combines guidance from [previous Devices and VRMM SOPs](#) (now archived) to apply to the new joint S&S division.
- 1.8 **NOTE: This is an interim SOP and is subject to change following the training scheduled for February 2024 and May 2025.**

2 Scope

To describe the procedures to be followed by members of staff in Safety & Surveillance (S&S) when

- responding to a request from the Police
- responding to a request from a coroner prior to inquest
- acting as independent witness to testing
- called to give evidence as a professional witness on behalf of MHRA or submit evidence to an inquest
- responding to coroners Regulation 28 reports to Prevent Future Deaths (PFDs).

3 Policy

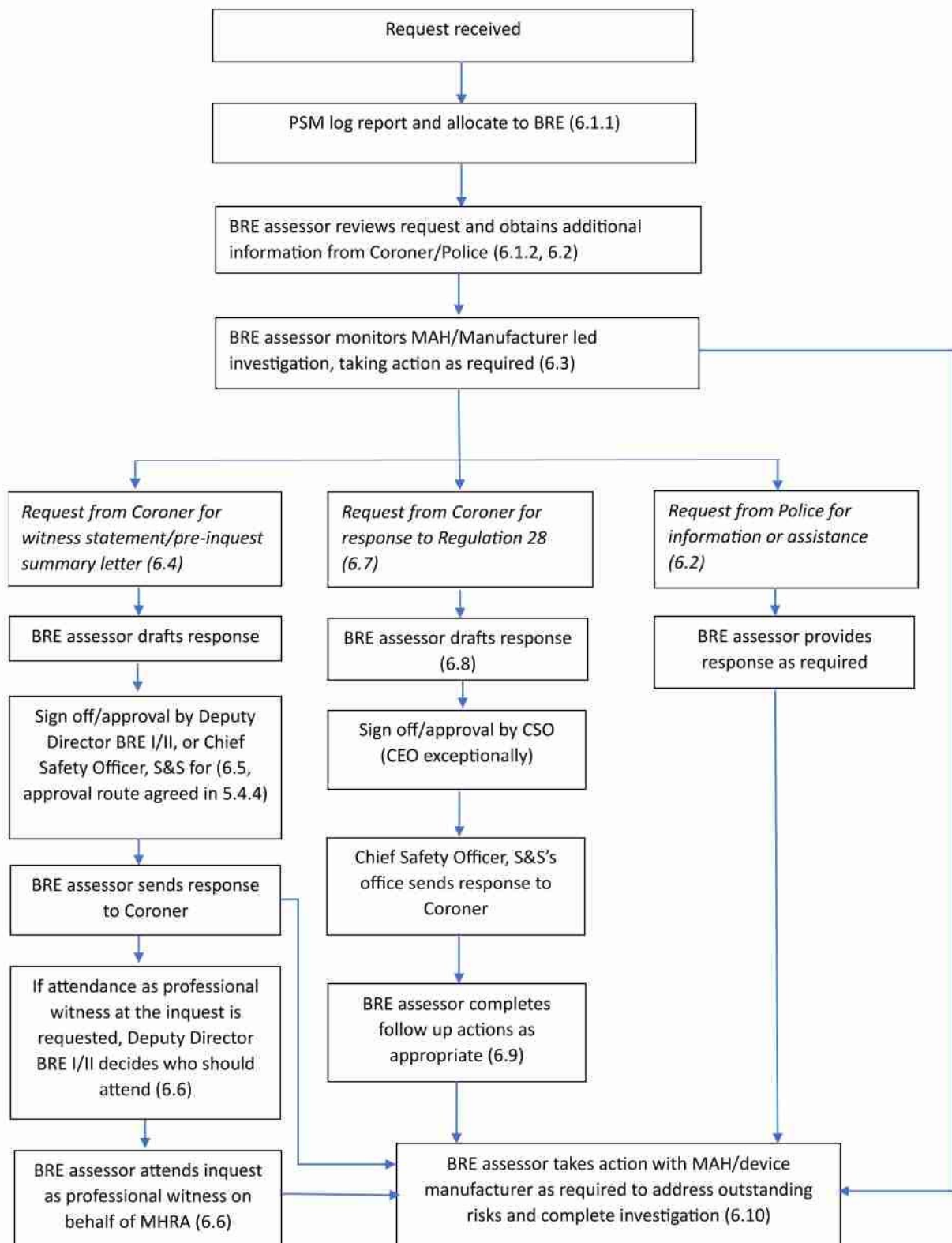
- 3.1.1 Paragraph 1 of Schedule 5 to the Coroners and Justice Act 2009 gives a coroner power to summon witnesses and to compel the production of evidence for the purposes of an investigation or an inquest. It is an offence to fail to comply with a notice under paragraph 1 of Schedule 5 requiring evidence to be produced or given. Witnesses at an inquest must give evidence under oath (or affirmation).
- 3.1.2 The coroner's Regulation 28 report is made under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013. Those to whom the report is made have to respond within 56 days of the report, unless the reporting coroner grants an extension.

4 Roles and responsibilities

- 4.1.1 In light of the importance of coroner's cases and police investigations, they must be treated by staff in the Division as high priority.

Benefit-Risk Evaluation (BRE) assessors and TAU Heads will lead the production of responses. Depending on the nature of the request, the Deputy Director BRE I/II may need to approve responses to cases before going to the Chief Safety Officer (CSO), or the Chief Executive Office (CEO) in exceptional cases (this may include high profile cases or where there is system wide impact), for final approval.

5 Flow chart



6 Procedure

6.1 Receiving and initial handling of request

6.1.1 Actions for PSM (Patient Safety Monitoring) team

6.1.1.1 Any correspondence requesting MHRA input from a coroner or the police usually arrives to the vigilance service mailbox [REDACTED]. The Vigilance Service & Data Provision team should log the request on the [S&S Coroner Requests and Queries Tracker.xlsx](#), and contact the relevant BRE HoU for allocation as well as the Head of Adverse Incidents and Signal Analysis (within PSM) to check whether the request is linked to an existing adverse incident report on the MHRA database. This includes requests for pre-inquest summary letters, witness statements and Regulation 28 responses.

6.1.1.2 If it is already on the MHRA database, the PSM assessor can upload a copy of any correspondence to the file or add a comment to the incident report.

6.1.1.3 If it is not already on the MHRA database, the PSM assessor should log a new incident report, add the tag "Coroner report" to the case folder and ensure that an acknowledgement is not sent out.

6.1.1.4 PSM assessor should notify the manufacturer / marketing authorisation holder if we have not received an incident report from them to ensure that they are aware.

6.1.1.5 The PSM assessor should send the corresponding incident report reference number to the assessors and teams involved in the response.

6.1.1.6 If the initial communication was received into any other PSM mailbox, the assessor should follow guidance in 6.1.1.1.

6.1.2 Actions for BRE

6.1.2.1 HoU allocates to a BRE assessor to take the lead and notifies the Deputy Director BRE I/II.

6.1.2.2 If the initial communication was received by a BRE assessor, they should email the HoU as soon as possible to inform them of the new request and forward to PSM to log as above.

6.1.2.3 BRE assessor creates a Sharepoint subfolder [here](#) to log the drafting of the formal response (if this has been requested) and links it to the incident report on the database.

6.2 Initial communication with the Coroner or Police

- 6.2.1 BRE assessor reviews our confidentiality responsibilities (additional guidance in [Annex A](#)).
- 6.2.2 Establish with the coroner or the police what they need. If a report is requested, confirm how regularly they would like to be updated and the preferred delivery route, i.e. post, email or both. If timeframes alter, the BRE assessor must advise the coroner or the police as soon as possible.
- 6.2.3 Template letters can be found in Annexes [B](#), [C](#) and [D](#).

6.3 Monitoring the investigation

- 6.3.1 BRE assessor should monitor progress of the manufacturer or marketing authorisation holder's investigation and request further information where required.
- 6.3.2 For events involving a medical device, in some circumstances MHRA may be requested to witness the manufacturer, or other organisation, undertake specific device tests.
 - BRE assessor should inform the HoU of the request and confirm appropriateness of attending. Examples of the type of manufacturer testing that can be carried out are outlined in [Annex E](#).
 - BRE assessor should establish the whereabouts of the device and remind everyone involved that the device is now a key piece of evidence and it now effectively becomes under control by HM Coroner. It must not be moved or tested/altered/destroyed without permission from the HM Coroner. Any destructive testing of the device should be carried out with prior approval from HM Coroner.

6.4 Preparing a MHRA pre-inquest summary letter or witness statement

- 6.4.1 BRE assessor and HoU agree what action is required and internal timescales for key stages. These should include:
 - completion of investigation
 - completion of first draft document
 - completion of final draft document.

Assessors should aim to provide a statement within 6 weeks of the request.

6.4.2 BRE assessor drafts the document to meet the coroner's requirements.

- For events involving medical devices, the document should address all technical aspects including design and performance and not include any discussion of clinical factors. In some circumstances, we might need to oversee initial or further testing.
- See [Annex F](#) for a summary of what should be included in the letter for an event involving a medical device. Templates for a witness statement for an event involving a medicine can be found [here](#). [Examples of previous responses](#) are available for review.

6.4.3 BRE assessor informs the HoU of progress at regular intervals. In general:

- the first draft of the document should be presented to the HoU for approval within 3 weeks of all necessary information becoming available;
- Review, editing and sign-off of the document should be completed as soon as possible, preferably within 3 weeks of completion of the first draft.
- Give the HoU regular feedback, especially if you run into any difficulties with deadlines. If extensive revision is required or complex technical or legal issues arise, the HoU should be advised that these timescales may not be met.
- If requested, provide regular updates to the Coroner throughout the investigation process.

6.4.4 BRE assessor presents brief overview at SMRM and confirms what level of sign off is required.

- Cases with potential for significant public health impact or public/media interest should be considered for CSO sign off. Other cases should be signed off by Deputy Director BRE I/II.

6.4.5 HoU reviews and amends the draft in conjunction with the BRE assessor. The Deputy Director BRE I/II should be updated on progress on request.

6.4.6 BRE assessor in discussion with HoU identifies who may need to review the draft document. This list may include:

- Other HoUs and BRE Assessors
- Medical BRE Assessors
- Regulatory Specialists
- Register of experts (appropriate members) or EAGs

- GLD

6.4.7 BRE assessor sends the draft document to agreed parties with a pre-determined time limit for feedback and comments.

6.4.8 BRE assessor revises draft following feedback, documenting suggestions and recording why they have/have not been adopted. Discuss “final draft” for approval with HoU.

6.5 Approval and submission of MHRA witness statement or pre-inquest summary letter

6.5.1 BRE assessor sends the finalised draft to Deputy Director BRE I/II, or CSO for approval (approval route agreed in [6.4.4](#)).

6.5.2 Deputy Director BRE I/II, or CSO approves the final draft. If further changes are required inform BRE assessor in an email and send tracked change comments on draft document.

6.5.3 If BRE assessor needs to make changes, follow steps from [6.4.8](#) onwards.

6.5.4 When the Deputy Director BRE I/II, or CSO signs off the approved version, BRE assessor signs and sends the final document to the Coroner or the police.

- BRE assessor re-confirms the delivery route (post, email or both) with Coroner or the police.
- If the document is being delivered via the post, the envelope should be marked “confidential”.
- If the document is being delivered via email, check the email address first with a test email, and then send it with “Confidential” in the subject line. Start of the main body of the email with “Confidential”. Use the built in Outlook official sensitive marking on the email. NOTE: Ensure document is sent via a secure route.

6.5.5 The witness statement/pre-inquest summary letter is the property of the coroner. Any requests from interested parties to obtain a copy of the document should be made to the coroner directly.

6.6 Attending an inquest as a witness

6.6.1 Following submission of a witness statement or pre-inquest summary letter, MHRA may be asked (summoned) to attend the inquest to give evidence as a

professional witness. Alternatively, there may be a summons without a pre-inquest summary letter.

- 6.6.2 MHRA may also be asked to attend pre-inquest review meetings, the purpose of which is to ensure that there is agreement that all the necessary witnesses have been called and information requests made and importantly that the deceased member's family are happy to proceed before the Inquest starts.
- 6.6.3 Attendance at Pre-Inquest Review Hearing and the Inquest itself can be remote or face to face depending on the from the coroner.
- 6.6.4 The BRE assessor who authored the summary letter or witness statement may be required to read the document or provide a verbal account and be questioned by the coroner and lawyers acting on behalf of the healthcare professionals, the health authority, or the family of the deceased. Therefore, the author must have an appropriate degree of knowledge, training and experience and (if the date of the inquest is known at the time the document is written) be available to attend.
- 6.6.5 All requests requiring evidence to be given to an inquest should be sent to the Deputy Director BRE I/II.
- 6.6.6 Deputy Director BRE I/II will make a decision on the most appropriate person to give evidence to the inquest (in most cases, the author of the document).
- 6.6.7 Preparation to attend an inquest as a witness is extremely important and appropriate preparation/training should be agreed with line managers. This would include a meeting with GLD to discuss need for legal representation at the Inquest.

6.7 Regulation 28 reports (Reports to Prevent Future Deaths) – initial actions

- 6.7.1 Follow guidance in section [6.1](#) on receipt of request.
- 6.7.2 BRE assessor sends an acknowledgement letter (if one has not already been sent). A template for the acknowledgement letter is in [Annex G](#).
- 6.7.3 If MHRA are informed of a Regulation 28 report which falls under S&S's areas of responsibility, but which has not been formally sent to the Agency:

BRE assessor sends an acknowledgement letter and asks if a formal Regulation 28 report should be anticipated.

- MHRA may provide a contribution to the formal response from another

organisation (e.g. DHSC) on request. The format and timescale for responding should be agreed with the organisation involved.

6.8 Preparing a response to a Regulation 28 report

- 6.8.1 Under Regulation 29, MHRA is under duty to give a response within **56 calendar days** of the Regulation 28 report being sent. The [Regulation 29 template](#) should be used for this response.
- 6.8.2 If for any reason it is not possible to respond before the deadline, an extension must be sought from the relevant coroner. A template for this letter is in [Annex H](#).
- 6.8.3 BRE assessor and HoU follow guidance in [section 6.4](#) to plan and draft a response. See [Annex F](#) for a summary of what may be included in the response relating to an event involving a medical device. [Examples of previous responses](#) relating to medicinal products and medical devices are available for review.
- 6.8.4 BRE assessor presents a brief overview at SMRM.
- 6.8.5 BRE assessor and HoU should consider:
- contacting DHSC, NICE, BNF or other relevant organisations if they have also received the Regulation 28 report, to discuss whether it would be appropriate to liaise over the response or share drafts
 - notifying the Group manager of PIQU (copying in the [REDACTED] mailbox) if the event involves a medicinal product, as many Regulation 28 reports will impact on the statutory product information
 - whether expert advice is required, for example from PEAG or IDWG
 - whether other parts of the Agency such as the Communications Division and DMRC need to be involved in the response, and whether a wider planning meeting with colleagues from other divisions is required. If so, BRE assessor to organise meeting within two weeks to discuss the regulatory options to prevent future deaths.
 - If a communication is agreed, inform the Risk Communications team so as it can be raised at the relevant planning meeting.
 - If regulatory action is agreed, consider the likelihood of media attention, particularly if the issue is sensitive or if restrictive action is being considered. If media attention is considered likely, inform the

Communications team as soon as possible so that a communications plan can be developed.

- 6.8.6 BRE assessor and HoU follow guidance in [section 6.4](#) to plan and draft a response. See [Annex F](#) for a summary of what may be included in the response relating to an event involving a medical device.
- 6.8.7 The response must include:
- Details of previous or proposed action with timescales for action; or
 - An explanation as to why no action is proposed
- 6.8.8 When drafting, bear in mind that all Regulation 28 report responses are sent to the Chief Coroner by the Coroner responsible for the case. In most cases the Chief Coroner will publish the reports and responses on the Courts and Tribunals Judiciary website. Refer to [Annex A](#) for guidance on confidentiality for events involving medical devices.
- 6.8.9 BRE assessor drafts the response and agrees with the HoU by no later than **day 28** from date of letter sent.
- 6.8.10 BRE assessor sends agreed draft Deputy Director BRE I/II for comment (copy in HoU).
- 6.8.11 Deputy Director BRE I/II provides any comments by no later than **day 35** from date of letter sent.
- 6.8.12 BRE assessor incorporates comments in final draft by no later than **day 42** and send for clearance from the CSO. There may be exceptional circumstances, such as a high profile case or where there is system wide impact, when the CSO may wish to obtain CEO sign off.
- 6.8.13 Following clearance, the CSO signs the reply (unless the CEO wishes to do so in exceptional circumstances) and it is sent out from the CSO's office. A copy of the reply will be sent to the MHRA Executive Office for information.

6.9 Actions following submission of a response to a Regulation 28 Report

- 6.9.1 BRE assessor and HoU ensure that any actions proposed in the response are completed.
- 6.9.2 If required, BRE assessor drafts an update to the Coroner with the outcomes of the actions undertaken. Agree with HoU and send to Coroner.

6.10 Completion of the investigation

- 6.10.1 BRE assessor takes action with MAH/device manufacturer as required to address outstanding risks and complete investigation.
- 6.10.2 BRE assessor ensures that all relevant documents are uploaded to the Sharepoint folder, updates and closes the record on the relevant database and notifies the Vigilance Service & Data Provision team () that the final response has been sent.
- 6.10.3 Vigilance Service & Data Provision team update the status of the record on the excel tracking sheet to "complete".

7 Competence

- 7.1 New members of staff will be made aware of the requirements of this SOP by their line managers. Appropriate training and preparation will be discussed and agreed with line managers for any member of staff attending an inquest as a witness.

8 Monitoring compliance

- 8.1 Internal deadlines will be agreed between the BRE assessor and HoU.
- 8.2 BRE assessor is responsible for ensuring that a response is provided within the relevant internal and external deadlines.

9 Glossary

The following key terms are used in this document:

Term	Definition of term
BRE	Benefit Risk Evaluation
CSO	Chief Safety Officer
GLD	Government Legal Department
HoU	Head of Technical Assessment Unit
HQA	Healthcare Quality and Access
IDWG	Interim Devices Working Group
PEAG	Pharmacovigilance Expert Advisory Group
PIQU	Product Information Quality Unit in HQA
PSM	Patient Safety Monitoring Team
S&S	Safety and Surveillance Division
SMRM	Signals, Messaging and Risk Meeting
SMT	BRE Senior Management Team

Annex A: Confidentiality

- The report may be released by the coroner, thus placing it in the public domain. Any sensitive information in the report will need to be released from any confidentiality agreements.
- If the information is **not** critical to the investigation and the manufacturer or MAH has requested for it **not** to be released in the public domain, we can send a separate document to the coroner where:
 - > words or sections are blanked out
 - > or we include a statement explaining that specific detail or sales data are commercially sensitive and their public release is not necessary to protect public health.
- As the report is made at the request of a coroner, copies may not be provided, or its content disclosed, to any third party without the coroner's prior agreement.

Annex B: Example initial letter to Coroner following request for evidence

Dear XX

Coroners and Justice Act 2009 – call for evidence following the Inquest into the death of XXXX

Thank you for your letter dated XXXXX, received on XXXXXX, requesting evidence to be submitted/given to the inquest into the death of XXXX.

We are giving the matter our full consideration and will arrange for evidence to be submitted to meet your deadline/ inform you in due course of the MHRA official who will attend the inquest.

In order for us to provide a comprehensive response, please provide the following additional detail:

- Missing item 1
- Missing item 2
- Missing item 3 etc

Yours sincerely

Annex C: Example initial letter to Coroner or the Police explaining remit of MHRA and the assistance we can provide (medical device)

Dear Sir/Madam,

About us

The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of Health. We are responsible for regulating all medical devices and medicines in the UK by ensuring they work and are acceptably safe.

How we can help you

We can help your investigations of incidents involving medical devices. However, our role is limited to the actions below.

- Ask the manufacturer of the medical device(s) to investigate and test the device(s).
- Witness the testing/inspection by the manufacturer or its representatives (in the UK only).
- Provide a summary letter with comments on the manufacturer's report of the investigation. This may include details such as the number of similar reported incidents on our database, and any related safety actions.
- Attend the coroner's court to give evidence if required. However, please note that where technical detail of the device is required, the manufacturer should be invited to provide evidence.

What we can't do

- test or inspect medical devices
- pay for independent tests.

Please contact me as soon as possible to discuss the details of your requirements.

Yours faithfully/sincerely,

Annex D: Alternative example initial letter to Coroner or the Police explaining remit of MHRA and the assistance we can provide (medical device)

Dear Sir/Madam,

Coroners and Justice Act 2009 – call for evidence following the Inquest into the death of XXXX

Thank you for your letter dated XXXXX, received on XXXXXX, requesting evidence to be submitted/given to the inquest into the death of XXXX.

Please find a summary below detailing the role of the MHRA Safety and Surveillance Division and an outline of the types of assistance that we can offer.

The Medicines and Healthcare Products Regulatory Agency is an executive agency of the Department of Health. As part of this, the MHRA Safety and Surveillance Division is responsible for protecting the public's health and safeguarding the interests of patients and users by ensuring that medicines, medical devices and equipment meet appropriate standards of safety, quality and performance and that they comply with relevant directives. Details on all the business areas of the agency can be found on the website www.mhra.gov.uk.

Where adverse incidents involving medical devices have been reported to other authorities, including the police, coroners and the Health and Safety Executive (HSE), we are able to provide the following assistance to that authority:

1. Liaise with the manufacturer of the medical device(s) and request that they investigate and test the device(s). As part of the manufacturer's investigation they may choose to have the device independently tested at a laboratory with specialist equipment. We can then request a report from the manufacturer summarising their findings, including the root cause of the device failure (if established), and provide this to the instructing authority.
2. Witness the above testing/inspection of device(s) by the manufacturer or its representatives in the UK only. Please note, we do not have the resources or specialist equipment to undertake our own testing/inspection of medical devices. Normally the manufacturer will undertake testing at their premises, which may be located overseas.
3. Produce a summary letter with comments on the manufacturer's report (if applicable). The summary letter may also provide details such as the number of similar reported incidents on our database, and any related safety actions that may be relevant to the device in question.
4. Attend the coroner's court to give evidence, if instructed.

In addition, we may issue safety information to the health service or advise the manufacturer to make design changes to their product to prevent similar occurrences in the future.

To assist us in an effective investigation, please advise us as soon as possible if you have any specific requirements, such as testing the device (e.g. whether destructive testing can be undertaken).

Thank you in advance for your assistance in this matter.

Yours faithfully/sincerely,

Annex E: Inspection and testing by the manufacturer (medical device)

The manufacturer may:

- Review the device log file to determine the sequence of events leading to the reported event.
- Test the device using the settings chosen at the time of the event. This is to determine whether it would work as intended in the chosen configuration. This may be done with calibrated equipment to an established testing schedule (manufacturing or maintenance based).
- If other devices were involved in the incident, then the testing should involve those devices.
- Test the device to determine whether it is operating as intended over its range of capability.

The need for additional testing may arise during the investigation.

Annex F: Content of a summary letter on a medical device

The word template letter with MHRA letterhead should be used, and the letter should be based on the following format:

Postal address of Coroner

FAO: Coroner (name of Coroner)

Date:

Coroner ref: (if applicable)

Our ref:

Dear (Name of Coroner)

A summary of the MHRA's investigation into a [manufacturer] [product] and its relation to the circumstances surrounding the death of [name of deceased] (DOC XX/XX/XXXX, DOD XX/XX/XXXX).

Introduction

Start the letter with an introduction to MHRA, who we are, what we do and why we have been involved in the case.

Synopsis of incident

This should include:

- a brief description of the circumstances leading to the death
- the date and circumstances by which the MHRA was informed of the death (including names and addresses)
- relevant clinical procedures and patient condition
- specific instructions received from HM Coroner (if applicable)
- Initial actions taken by MHRA (e.g. contacting manufacturer including names and addresses).

Device Details

List the identification details of the device. This should include (as applicable):

- Medical device type
- Model name
- Model number/Catalogue number
- Manufacturer
- UK distributor(s)
- Manufacture date
- Serial number
- LOT/batch number

- Software number

Provide a brief description of the device including the following:

- description of the function of the device and the clinical procedures for which it is used
- relevant features of its design, construction, presentation and use
- CE/UKCA-marking status and indication of what that implies
- date introduced into clinical use in the UK and an indication of extent of use (e.g. numbers used in UK / worldwide, number of UK centres using it, etc)
- if relevant, any device standards with which the product complies, with an indication of the status or relevance of standards quoted;

The same information should be provided for accessories used where relevant.

Inspections and tests witnessed by the MHRA

This should include:

- an explanation of the MHRA's involvement in monitoring and reviewing inspections and tests;
- an explanation of all inspections and tests undertaken, noting agreement of protocols by other parties (e.g. external test laboratories, manufacturer, hospital, HM Coroner);

NB All inspection and tests undertaken or commissioned by the MHRA must be carefully planned in advance, especially where destructive testing is being considered and be robust with respect to calibration, traceability and scientific integrity, as the validity and accuracy of results may be challenged in cross-examination.

- justification for any destructive testing carried out;

NB Destructive testing should have been authorised in advance by HM Coroner.

- the results of inspections and tests undertaken. These may be presented in an Appendix, with a summary in the body of the report.

Investigations by the Manufacturer

This section should include:

- a description and summary of all additional unwitnessed inspection and tests undertaken by the manufacturer.
- a summary of the manufacturers conclusions.

Prevalence of the problem

This section should include:

- a summary of previous reported incidents of the same nature, including relevant information on:
 - o fatalities
 - o failure modes
 - o conclusions reached
 - o advice given to users
 - o corrective actions
 - o MHRA advisory notices.
 - o Evidence obtained through consultation with other Competent Authorities
- brief findings from any literature search or trend analysis (anecdotal or un-attributable evidence should normally be omitted);

If the root cause was identified as a recognised complication associated with the clinical procedure, the following should be included:

- o an indication of relevant content of the Instructions for Use;
- o information on factors that can influence the occurrence of relevant complications
- o information on the incidence of relevant complications seen with the product.

MHRA observations

This section should include:

- BRE assessor's observations on the evidence provided above, highlighting any evidence that indicates shortcomings in product design, instructions for use, indications or contraindications for use or the presentation of the device
- objective observations on the manufacturer's conclusions;
- any action taken by the MHRA, the manufacturer or others as a result of the incident.
- The outcome of any discussions with clinical assessors or external clinical experts.

Discussion of clinical details and comments on other reports (e.g. from pathologists or clinicians) should be avoided.

Conclusions

All results of inspections and tests should be summarised concisely, highlighting the major observations. Conclusions should be stated clearly and concisely, paying particular attention to:

- whether the product performed as intended,
- the suitability of product design,
- the adequacy of the instructions for use.

The final paragraph should offer further assistance if required and request information on the date, place and outcome of the inquest.

References

Appendices

Appendices may include results, tables, graphs and photographs. Relevant information/documents such as a copy of the manufacturer's report (may be more than 1 if multiple products are involved), IFUs, FSNs and similar should also be included where they are referred to in the report.

Annex G: Example acknowledgement letter to Regulation 28 report

Dear XX

Coroners and Justice Act 2009 – Regulation 28 Report following the Inquest
into the death of XXXX

Thank you for your letter dated XXXXX, received on XXXXXX, enclosing your Report
under Regulation 28 following the Inquest into the death of XXXX.

We are giving the matters you have raised full consideration and will respond in due
course.

We note that the deadline for response is XXXXXX.

Yours sincerely

Annex H: Example letter requesting an extension to the deadline to respond to a Regulation 28 report

Dear XX

Thank you for your letter dated XXXXX, received on XXXXXX, enclosing your Report under Regulation 28 following the Inquest into the death of XXXX.

I would be most grateful if we could request a X week extension to the XX deadline to enable us to provide a response that has been informed by XXXX?

I look forward to hearing from you.

Yours sincerely