GHTF SG2 Guidance:
Group work output presentation
SG2
Post-market Surveillance & Vigilance

- SG2 is charged with the task of developing harmonized manufacturers’ adverse event reporting and other forms of post-market surveillance for countries with existing medical device regulations and those countries in the process of developing medical device reporting regulations.

- Significant elements of post-market surveillance/vigilance involve information collection and assessment, risk analysis, decision/implementation, and safety information distribution.

Reference: section 9.2 GHTF/AHWG-GRM/N1R13
Vigilance is the reporting and investigation of adverse events (AE) and incidents. Both the manufacturer and the Regulatory Authority play major roles.

GHTF SG2 now prefers to use the term “Adverse Event Reporting”
Post-Market Surveillance

- Post-Market Surveillance is the collection of information on the quality, safety or performance of Medical Devices after they have been placed in the market.

- A balanced Post-Market Surveillance system will contain an appropriate mix of proactive and reactive activities.
Post-market Surveillance & Vigilance

Post-Market Surveillance
Information is used for:
- Injury prevention
- Development of standards
- Regulatory refinement
- Product improvement

Vigilance
(adverse event investigation & reporting)

Post Market Surveillance
Summary: SG2 PMS/Vigilance activities, SG2 Documents & Links to International Standards (*)

(*) section 9.2 GHTF/AHWG-GRM/N1R13
SG2 Guidance on AE Report Handling & NCAR Exchange Program


GHTF SG2 Guidance:
Reporting of Medical Device Adverse Events

Table of Contents:
- Section 1  Scope
- Section 2  Definitions
- Section 3  Adverse Event Reporting Guidance
- Section 4  Exemptions
- Section 5  Use error
- Section 6  To Whom to Report
- Section 7  Reporting Timeframes
- Section 8  Report Data Set

Annexes:
- A. Universal data set
- B. Timing of AE report
- C. Trends
- D. Use error
Reporting Criteria and Exemptions

Adverse Event

Report?

N

Y

Document rationale for not reporting

N

Trend?

Y

To which NCA(s)?

Within what timeframe?

What Information?

Manufacturer’s Investigation

SG2 N54 Sects 3, 4 & 5

SG2 N54 Annex C

National Regulator (NCA)

SG2 N8

SG2 N79

National Regulator

NCA Report?

Y

Other Participating National Regulators

SG2 N38

Manufacturer or Authorised Representative

SG2 N54 Sect 6

SG2 N54 Sect 7

SG2 N54 Sect 8
GHTF N54 Section 3.0
Three Basic Reporting Criteria

- An EVENT must have occurred
  AND
- The manufacturers device was ASSOCIATED with the event
  AND
- The event led to the death or SERIOUS INJURY of a patient user or other person, OR might lead to death or serious injury if the event re-occurs
EVENT

- Malfunction or deterioration
- Inadequate design or manufacture
- Inaccuracy in labeling
- Significant public health concern
- Other information from testing or literature
- A change in trend
ASSOCIATION (WITH THE DEVICE)

- When the association with the device is difficult to establish, the manufacturer must rely on:
  - Opinion from healthcare professional
  - Previous similar events
  - Other information available to the manufacturer
- If there is any doubt, assume that the device was associated with the event.
SERIOUS INJURY

– Life threatening illness or injury
– Permanent (irreversible) impairment of a body function or permanent damage to a body structure
– A condition requiring medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure
GHTF N54 Section 4.1- 4.8
Exemption Rules

Whenever any one of the following exemption rules is met, the adverse event does not need to be reported to a NCA by the manufacturer.
Exemption Rule 1

1) Deficiency of a new device found by the user prior to its use

Deficiencies of devices that would always be detected by the user and where no serious injury has occurred, do not need to be reported
Exemption Rule 1 Example

1) Deficiency of a new device found by the user prior to its use

Example-
User performs an inflation test prior to inserting the balloon catheter in the patient as required in the instructions for use accompanying the device. Malfunction on inflation is identified. Another balloon is used. Patient is not injured
2) Adverse event caused by patient conditions

When the manufacturer has information that the root cause of the adverse event is due to a patient’s condition, the event does not need to be reported. These conditions could be preexisting or occurring during device use.
Exemption Rule 2 Example

2) Adverse event caused by patient conditions

Example-
Revision of an orthopedic implant due to loosening caused by the patient developing osteoporosis
Exemption Rule 3

3) Service life or shelf life of the medical device
When the only cause for the adverse event was that the device was used beyond its service life as specified by the manufacturer and the failure mode is not unusual, the adverse event does not need to be reported.
3) Service life of the medical device

Example-
Loss of sensing after a pacemaker has reached end of life. Elective replacement indicator has shown up in due time according to device specification. Surgical explantation of pacemaker required.
Exemption Rule 4

4) Malfunction protection operated correctly

Adverse events which did not lead to serious injury or death, because a design feature protected against a malfunction becoming a hazard, do not need to be reported.
Exemption Rule 4 Example

4) Malfunction protection operated correctly

Example-
After a malfunction of an infusion pump it gives an appropriate alarm and stops (in compliance with relevant standards). There was no injury to the patient
5) Negligible likelihood of occurrence of death or serious injury

Adverse events which could lead, but have not yet led, to death or serious injury, but have a remote likelihood of causing death or serious injury, and which have been established and documented as acceptable after risk assessment do not need to be reported.
Exemption Rule 5 Example

5) Negligible likelihood of occurrence of death or serious injury

Example-
Manufacturer of pacemaker released on the market identified a software bug and determined that the likelihood of occurrence of a serious injury with a particular setting is negligible. No patients experienced adverse health effects.
Exemption Rule 6

6) Expected and foreseeable side effects which meet all the following criteria:

- Clearly identify in the manufacturer’s labeling
- Clinically well known and having a certain qualitative and quantitative predictability when used & performed as intended
- Documented in the device master record, with risk assessment prior to occurrence
- Clinically acceptable in terms of patient benefit are not reportable
Exemption Rule 6 Example

6) Expected and foreseeable side effects

Example-
Placement of central line catheter results in anxiety reaction and shortness of breath. Both reactions are known and labeled side effects.
Exemption Rule 7

7) Adverse events described in an advisory notice

Adverse events (AEs) that occur after a manufacturer has issued an advisory notice need not be reported individually if specified in the notice. Advisory notices include removals from the market, corrective actions, and product recalls. The manufacturer should provide a summary report, the content and frequency of which should be agreed with the relevant NCA.
Exemption Rule 7 Example

7) Adverse events described in an advisory notice

Example-
Manufacturer issued an advisory notice and recall of a coronary stent that migrated due to inadequate inflation of an attached balloon mechanism. Subsequent examples of stent migration were summarized in quarterly recall reports and individual events did not have to be reported.
Exemption Rule 8

8) Reporting exemptions granted by NCA

Upon request by the manufacturer and agreement by NCA common and well-documented events may be exempted from reporting or changed to periodic summary reporting.
GHTF N54 Section 4
Other considerations

- If a NCA requires reporting a specific type of event due to a significant public health concern, the exemptions are no longer applicable.
- Adverse events which are subject to an exemption become reportable to the NCA if a change in trend (usually an increase in frequency) or pattern is identified.
Use Error: Section 5 (N54) + appendix D
Act, or omission of an act, that has a different result to that intended by the manufacturer or expected by the operator.

Examples -
- Despite proper instruction and proper design according to manufacturers analysis operator presses wrong button
- Operator enters incorrect sequence and fails to initiate an action such as infusion
Abnormal Use:
Act, or omission of an act by the operator or user of a medical device as a result of conduct that is beyond any reasonable means of risk control by the manufacturer.

Examples:
- Use of a medical device in installation prior to completing all initial performance checks as specified by the manufacturer.
- Continued use of a medical device beyond the manufacturers defined planned maintenance interval as a result of user’s failure to arrange for maintenance.
Use Errors & Abnormal Use

Note - Foreseeable misuse that is warned against in the instructions for use is considered abnormal use if all other reasonable means of risk control have been exhausted.
Use Error - Reportability

- Use errors related to medical devices, which did result in death or serious injury or serious public health threat should be reported by the manufacturer to the National Competent Authority.
Use Error - Reportability

- Use errors related to medical devices which did not result in death or serious injury or serious public health concerns, need not be reported by the manufacturer to the national competent authorities.

- Use errors become reportable by the manufacturer to the national competent authorities when a manufacturer:
  - Notes a change in trend that can potentially lead to death or serious injury of public health concern.
  - Initiates corrective action to prevent death or serious injury or serious public health concern.
Abnormal Use - Reportability

- Abnormal use need not to be reported by the manufacturer to the national competent authority under adverse event reporting procedure. Abnormal use should be handled by the healthcare facility and appropriate regulatory authorities.
- If manufacturers become aware of instances of abnormal use, they may bring this to the attention or other appropriate organizations and healthcare facility personnel.
The Universe of Device Associated Adverse Events

- R = Report
- NR* = No Report

- = Death
- = Serious Injury
- = Malfunction
- /could have resulted SI
AE Trend Reporting

- Adverse events specifically exempted from reporting become reportable if there is a change in trend (usually an increase in frequency) or pattern is identified.
- The SG2 document on trend reporting describes the criteria for identifying a significant increase in the rate of adverse events.
- Not a handbook of statistical techniques.
- Provides guidance to assist manufacturers to perform trending.
AE Trend Reporting

- Example of an upward shift in trend

* normal Range of Variance
To Which NCAs to Report?

Adverse Event

Report? [Y] [N]

- Manufacturer’s Investigation
- SG2 N54 Sects 3, 4 & 5
- SG2 N54 Annex C

- Trend? [Y] [N]
  - Document rationale for not reporting
  - (Report must be submitted)

- To which NCA(s)?
  - SG2 N54 Sect 6
  - SG2 N54 Sect 7
  - SG2 N54 Sect 8

- National Regulator (NCA)
  - SG2 N8
  - SG2 N79

- National Regulator Report?
  - NCA Report? [Y] [N]
    - Other Participating National Regulators
  - SG2 N38

Manufacturer or Authorised Representative
Adverse Events must be reported to a National Competent Authority (NCA) according to applicable requirements in each jurisdiction. NCAs should provide a contact point to manufacturer from reporting.

SG2 considered several options that might resolve this situation, including the establishment of a global database for submission of adverse event reports.
Within What Timeframe?

Adverse Event

Manufacturer or Authorised Representative

Manufacturer’s Investigation

SG2 N54 Sects 3, 4 & 5

SG2 N54 Annex C

Report?

N

Document rationale for not reporting

N

Trend?

Y

(Report must be submitted)

To which NCA(s)?

SG2 N54 Sect 6

SG2 N54 Sect 7

SG2 N54 Sect 8

National Regulator (NCA)

Within what timeframe?

SG2 N8

SG2 N79

National Regulator

Other Participating National Regulators

What Information?

Y

N

Report?

Y

(Report must be submitted)
Adverse events that result in unanticipated death or unanticipated serious injury or represent a serious public health threat must be reported immediately by the manufacturer.

All other reportable events must be reported as soon as possible by the manufacturer, but not later than 30 elapsed calendar days following the date of awareness of the event.
Reporting Timeframes

- **Immediately:** For purposes of adverse event reporting, immediately means as soon as possible, but not later than 10 elapsed calendar days following the date of awareness of the event.

- **Serious public health threat:** Any event type, which results in imminent risk of death, serious injury, or serious illness that may require prompt remedial action.
Reporting Timeframes

- **Unanticipated:** A death or serious injury is considered unanticipated if the condition leading to the event was not considered in a risk analysis performed during the design and development phase of the device. There must be documented evidence in the design file that such analysis was used to reduce the risk to an acceptable level.
What Information (Dataset)?

Adverse Event

Manufacturer or Authorised Representative

Manufacturer’s Investigation

SG2 N54 Sects 3, 4 & 5

SG2 N54 Annex C

Report?

Document rationale for not reporting

Trend?

(Y N)

N

To which NCA(s)?

Within what timeframe?

N

N

N

National Regulator (NCA)

SG2 N54 Sect 6

SG2 N54 Sect 7

SG2 N54 Sect 8

SG2 N8

SG2 N79

National Regulator

NCA Report?

Y

N

Other Participating National Regulators

SG2 N38

What Information?
Report Data Set

- **Event information:** Dates, Reporter details, Healthcare facility details, Patient details, Event type and description, Notified CA’s, Resolution description

- **Device Information:** Manufacturer, Generic device group, Disposition, Results of analysis, Corrective action taken.

- **Other:** Comments, Notified Body details, CAs notified of Corrective action
Case study:

Implementation of SG2 Adverse Event Reporting Guidance in Australia
Changes Required

- The way that **YOU** and your agency thinks about regulation.
- Then change:
  - The Law
  - The Regulations (legal instruments)
  - National guidelines
  - Administrative practice
People to Convince

- Yourself
- Your colleagues and your superiors
- Peak advisory bodies (medical associations, hospital associations etc)
- Politicians (and the public)
- Local industry (?)
# Basic Reporting Criteria, Exemptions 1-3

<table>
<thead>
<tr>
<th>N54 Part</th>
<th>Description</th>
<th>Status in Australia</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sections 3.1-3.3</strong></td>
<td>Definition of reportable event, basic reporting criteria</td>
<td>Implemented in the law S41FN, S41MP, examples and plain English definition in TGA Guidance 11</td>
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</table>

### Exemptions

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
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<tr>
<td>4.1</td>
<td>Deficiency of a New Device Found by the User Prior to its Use</td>
<td>Implemented, but TGA Guidance says &quot;always instead of &quot;normally&quot;.</td>
</tr>
<tr>
<td>4.2</td>
<td>Adverse Event Caused by Patient Conditions</td>
<td>Implemented in TGA Guidance</td>
</tr>
<tr>
<td>4.3</td>
<td>Service Life of the Medical Device</td>
<td>Implemented in TGA Guidance</td>
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</table>
## Exemptions 4-8

<table>
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<th>N54 Part</th>
<th>Description</th>
<th>Status in AU</th>
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<tbody>
<tr>
<td><strong>Section 4.4</strong></td>
<td>Protection Against a Fault Functioned Correctly</td>
<td>Implemented in TGA Guidance</td>
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<tr>
<td><strong>Section 4.5</strong></td>
<td>Remote Likelihood of Occurrence of Death or Serious Injury</td>
<td>Implemented in TGA Guidance</td>
</tr>
<tr>
<td><strong>Section 4.6</strong></td>
<td>Expected and Foreseeable Side Effects</td>
<td>Implemented in TGA Guidance</td>
</tr>
<tr>
<td><strong>Section 4.7</strong></td>
<td>Adverse Events Described in an Advisory Notice</td>
<td>Implemented in TGA Guidance</td>
</tr>
<tr>
<td><strong>Section 4.8</strong></td>
<td>Reporting Exemptions Granted by NCA</td>
<td>Implemented in TGA Guidance</td>
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### Other Sections

<table>
<thead>
<tr>
<th>SG2 Doc</th>
<th>Description</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Section 5</strong></td>
<td>Use Error Exemptions</td>
<td>Not implemented, user errors are reportable in Australia - this is explicit</td>
</tr>
<tr>
<td><strong>Section 8</strong></td>
<td>Universal Dataset</td>
<td>Implemented in TGA Guidance, minor local variations: ARTG#, ARTG Manufacturer#</td>
</tr>
<tr>
<td><strong>Section 7</strong></td>
<td>Timing for Adverse Event Reports</td>
<td>Implemented in the Medical Devices Regulations: Difference - &quot;Immediate Reports&quot; in 2 calendar days. &quot;Death and Serious Injury Reports&quot; in 10 Calendar Days</td>
</tr>
<tr>
<td>Annex C</td>
<td>Trending of Adverse Event Reports</td>
<td>Implemented, trending mentioned in TGA Guidance</td>
</tr>
</tbody>
</table>
Conclusions:

- Was it easy?....................................NO
- Was it hard work?..........................YES
- Was it worth the trouble?..............YES!
GHTF SG2:
National Competent Authority Report Program
Map of SG2 Guidance on AE Reporting

Manufacturer or Authorised Representative

Manufacturer’s Investigation

Report?

To which NCA(s)?

Within what timeframe?

What Information?

SG2 N54 Sects 3, 4 & 5

SG2 N54 Annex C

Document rationale for not reporting

(Report must be submitted)

Trend?

National Regulator (NCA)

National Regulator

Other Participating National Regulators

SG2 N79

SG2 N8

SG2 N38

N

Y

N

Y

Adverse Event

SG2 N54 Sect 6

SG2 N54 Sect 7

SG2 N54 Sect 8
Handling Adverse Event Reports: NCA Systems

- Manufacturer Reports
- User Reports
- Other P.M. Surveillance Information

- SG2 N8
- SG2 N79

- National Regulator

- Other Participating National Regulators

NCA Report? Y
Handling Adverse Event Reports: Confidence

“A good reporting culture … can only be achieved through **confidence between all parties concerned**. The question will always remain; what happens to data handed into the system? Can everybody along the line be trusted? Will the information be properly treated? As important as confidential and discrete handling and treatment of data, will be the way conclusions are drawn. What information is to be released and used, and how will this be done.”
Handling Adverse Event Reports:
Risk Assessment

RISK = Incidence x Hazard

- A hazardous event that occurs infrequently constitutes a LOW RISK
- An event that occurs often but has few or no safety implications constitutes a LOW RISK
Handling Adverse Event Reports: Risk Assessment for public servants

- There may be other factors that affect the outcome of risk assessment.
- These may be local or global considerations.

\[
\text{RISK} = \text{Incidence} \times \text{Hazard} \times \text{Public Concern}
\]
Handling Adverse Event Reports: Risk versus Benefit

- Australian road “TOLL”
  - 14,400,000 registered vehicles
  - 600,000 reported crashes (4.16%)
  - 200,000 reported injuries (1.38%)
  - 22,000 serious injuries (0.15%)
  - 1600 deaths (0.01%)
Handling Adverse Event Reports: Risk versus Benefit

- What “toll” is the public willing to pay for the benefit of using:
  - Pacemakers?
  - Heart valves?
  - Hip implants?
  - Catheters?

- Does the “risk taker” benefit from taking the risk?
Handling Adverse Event Reports: Risk Assessment

- There is no “silver bullet”
- Every ISSUE should receive individual risk assessment
- When difficult, seek help:
  - Medical experts
  - Other regulators
  - Manufacturer
NCAR
Hazards Associated with Reporting

- Public release of CONFIDENTIAL information
- Inappropriate release of information
- Misinterpretation of the issue
- Over-reaction to an issue
- Under-reaction to an issue
## Participation: Pre-requisites

<table>
<thead>
<tr>
<th>Participant Level</th>
<th>Associate Type of Information Sought by Participant</th>
<th>Full Type of Information Sought by Participant</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Associate</td>
<td>Public</td>
</tr>
<tr>
<td></td>
<td>Full</td>
<td>Confidential</td>
</tr>
<tr>
<td><strong>Prerequisites</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Possible Admin. Charge</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Working Reporting System</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Training</td>
<td>Yes #</td>
<td>Yes *</td>
</tr>
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</table>

# Training regarding GHTF N9 and N20 only. * Full Training
## Participation: Commitments

<table>
<thead>
<tr>
<th>Participant Level</th>
<th>Associate</th>
<th>Full</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of Information Sought by Participant</td>
<td>Public</td>
<td>Confidential</td>
</tr>
</tbody>
</table>

A commitment to:

<table>
<thead>
<tr>
<th>Confidentiality</th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Participation</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Single Contact Point</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Must be NCA</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Participation:
Important Commitments

- Must treat reports labelled “Confidential”

STRICTLY CONFIDENTIAL

- Must use form N79:
  - Ensures complete information
  - Prevents duplication
  - Protects sender

- Must not “send on” reports to non-participants.
Participation:  
Sending to non participants
Most of the information provided during this session is available in document N79R8:2006 at www.ghtf.org/sg2/final
Getting started

An NCAR tells other regulators about device issues that they do not already know about

There are 10 criteria to consider before generating an NCAR

**NOTE:** *Criteria considerations can clarify that no NCAR is needed*
1. Consider: **Seriousness**
not serious = no NCAR

Seriousness is determined by:
- A technical or clinical assessment
- The actual or potential impact to patients and users
- The difficulty in recognizing the issues and how to prevent or mitigate them
2. Consider: **Unexpectedness by itself = no NCAR**

Unexpected because of:

- a lack of historical information; rare
- an increase in frequency of occurrence
- a change in the situation in which it’s occurring
- a change in the outcome
3. Consider: **Vulnerable Pop.**

Is any special population at increased risk for adverse events?

If yes, can you define it? Such as:

- Age related – pediatric, geriatric
- Immune status – pregnancy, illness
4. Consider: Preventability

Can the issue be prevented or minimized?

Do you have recommendations for preventing or minimizing the issue?
5. Consider: **Public Percept.**

Sometimes the public perception* of an issue makes it appear “serious”

*All NCARs should be perceived as or considered “serious”
6. Consider: **Risks & Benefits**

Do established risks and benefits related to the device address the issue?

Are there well recognized and established standards of practice related to the use of the device?

Are there alternative devices available for use?
7. Consider: **Lack of Data**

Do you have scientific data on long term effects?

Do you have baseline data for comparison?

Is there national or international consensus on the issues and their resolution?
8. Consider: **Repeated issues**

Has this issue been identified before?

What new information do you have to share?

How will a new NCAR change what is already being done?
9. Consider: **Written notifications already exist**

No NCAR is needed when the issue is already well published and publicly available.

An NCAR might be appropriate when you get new information that is not otherwise publicly available.

The new information should be clearly described and easily found.
10. Consider: How will the NCAR help?

When the manufacturer’s efforts are sufficient = no NCAR
When you have no new information about the issue = no NCAR
When you have identified a new serious device issue, or have additional information of regulatory significance = send NCAR
The final decision is yours

Ultimately each regulator decides if and when to send an NCAR.

Too many NCARs = loss of attention
Too few NCARs = loss of information
About the NCAR document

An NCAR is for exchange of information between NCAR participants only, and should not be made public.

The NCAR format provides for consistency and familiarity with reported information.

Use “NA” in boxes where data is not applicable
1. **Is this report confidential?**

This form should be used for the exchange of information.

<table>
<thead>
<tr>
<th>1. Is this report confidential?</th>
<th>Yes [ ] No [ ]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference and Reporter Data</td>
<td></td>
</tr>
</tbody>
</table>

Check Yes [x] only when the NCAR has information that is not already public.

If the NCAR includes both public and confidential information, clearly identify what information is considered confidential.
Assigned by the originating regulator:

- Always begin with your 2 letter ISO* Country code (*see ISO 3166)
- Add –YYYY-MM-DD- for the year, month and day
- Last is the 3 digit sequence number; start each new year with 001

E.g., US-2007-10-08-030
3. Local NCA # = national tracking #
4. Related NCAR # = list of any NCARs sent on the same issue
5. Mfr Ref/Recall No = internal tracking # relating to corrective action or recall
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>6.</td>
<td><strong>Sent by</strong>: (Name and Organization)</td>
</tr>
<tr>
<td>7.</td>
<td><strong>Contact person</strong>: (if different from #6)</td>
</tr>
<tr>
<td>8.</td>
<td><strong>Tel:</strong></td>
</tr>
<tr>
<td>9.</td>
<td><strong>Fax:</strong></td>
</tr>
<tr>
<td>10.</td>
<td><strong>E-mail:</strong></td>
</tr>
</tbody>
</table>

- **6. Sent by** = who sent the NCAR
- **7. Contact person** = who will answer any questions, if not #6.
- **8 – 10. Telephone, Fax, and E-mail information** = how to reach the person who can answer any questions about the NCAR
Device Data

11. Generic name/ kind of device = a general & short device descriptor; e.g., defibrillator; wheelchair; suture

12. Nomenclature id = the name of the coding system you use, if any

13. No. - the specific code number for the subject device, if any
More Device Data

14. Trade Name and Model* = common product identifiers. *Note: 25c. also asks for other trade names used

15. Software version – e.g., FreeWare V2.1

16. Serial No.: & 17. Lot/batch No.: = unique product identifiers
18. Manufacturer Info.

Informs:

- **who** made the device,
- **where** the device was made, and
- a **contact** at the manufacturer

Optional: Use only when contact information is different from 18.

19. Authorized rep (if different from 18):
Country:
Full Address:
Contact:
Tel:
Fax:
E-mail:
CAB = conformity assessment body
Conformity assessment includes testing, inspection and certification of products, processes and persons.
Notified bodies carry out the tasks pertaining to the conformity assessment procedures
21. Device approval status & Risk Class

21a. **Device approval status** = the device was or was not approved for marketing

21b. **Risk Class** = the device is classified as a low, medium or high risk.

*Risk Class is not globally harmonized at this time. Generally, the higher the risk, the higher the risk class #.*
22. **Action Taken**

*Action taken* identifies what the NCA or the MFR has done.

- Check all boxes that apply.
- Use the “other” option as needed, and include a brief description.

7. Action taken:
   - [ ] None
   - [ ] Safeguard Action
   - [ ] Field Safety Corrective Action
   - [ ] Other (specify)
Event Data

23a. Background and reason for this report = Description of what the device issues are and what impact they have on patients or users

23b. Investigation complete? Y or N - Confirms if the investigation about the reported issue is complete or not
More Event Data

24a. **Conclusions** = the findings of the device investigation. Attach any documents and include web addresses when possible.

24b. **Have the manufacturer’s actions been made public?** Y or N

24c. **Tells if you will coordinate the investigation** - Y or N
Recommendations & global information

25a. Recommendations = what you want recipients to do with the information
25b. Known to be in the Market… = a list of countries where device is known to be marketed
25c. Also marketed as = list names different from #14.
Report distribution
NCAR Secretariat: MDV@hc-sc.gc.ca

26a. Mark all that apply.

This report is being distributed to:
[ ] The NCAR Secretariat for further distribution to FULL NCAR PARTICIPANTS.
[ ] The NCAR Secretariat for further distribution to ALL NCAR PARTICIPANTS.
[ ] EEA states, EC, and EFTA
[ ] The following targeted NCAs:
[ ] The manufacturer / authorized rep.:

26b. Complete only when your NCAR #s are not sequential

26b. The last GHTF-NCAR distributed by this NCA was (>>>>>
NCAR Program:
Procedures and Statistics
NCAR Exchange Program
- Procedures

- NCA Report number format:
  CC-YYYY-MM-DD-###, where:
  - CC is the 2-letter ISO code for the NCA
  - YYYY-MM-DD is the year-month-day
  - ### is the sequential numeric identifier for the report
NCAR Exchange Program
- Procedures

- Submit to NCAR Secretariat (NCAR-Sec) at GHTF.NCAR@tga.gov.au
- Prefer N79 form, MS-Word (.doc) format
- NCAR-Sec reviews report:
  - NCA Report Number correct?
  - Previously submitted? Other errors?
NCAR Exchange Program - Procedures

- 2 mailing lists:
  - NCARs originating in Europe
  - NCARs originating in AU, CA, HK, JP, US

- Forwarded with filename: CC-YYYY-MM-DD-###_Company-Name_Device-Name.doc
NCAR Exchange Program
- Procedures

- NCARs may be:
  - For your information
  - For your action
    - Recalls, Corrective Actions
    - Safety Alerts
    - Confidential requests from an NCA for information concerning an investigation
NCAR Exchange Program - Procedures

- You may not:
  - Release the information outside your NCA
  - Publish the information on the internet
  - Contact the company for info, if NCAR confidential
NCAR Exchange Program
- Procedures

- Important notes:
  - Single point of contact for NCA
  - Responsibilities
  - Field 1, Confidentiality
  - Extent of device distribution
NCAR Performance/Statistics to end September 2012.
NCARs Exchanged (total = 2,439)

Number of NCARs

- 2009: 281
- 2010: 287
- 2011: 291
- 2012: 291

Exchanged

Year: 1999 - 2012
Numbers of NCARs Represented by Device Sectors
Total Number of NCARs Represented by Actions Taken

- Field Correction, 828, 36%
- NCA Investigation, 35, 1%
- Recall, 1103, 48%
- Safety Alert, 347, 15%
- Safeguard Clause, 3, 0%
NCARs with Software-Related Corrective Actions

- Yes
- No
Numbers of NCARs that are related to IVDDs

- 1999: IVDD 1, Non-IVDD 36
- 2000: IVDD 4, Non-IVDD 75
- 2001: IVDD 5, Non-IVDD 150
- 2002: IVDD 10, Non-IVDD 121
- 2003: IVDD 32, Non-IVDD 124
- 2004: IVDD 32, Non-IVDD 96
- 2005: IVDD 46, Non-IVDD 129
- 2006: IVDD 32, Non-IVDD 153
- 2007: IVDD 19, Non-IVDD 155
- 2008: IVDD 20, Non-IVDD 175
- 2009: IVDD 29, Non-IVDD 142
- 2010: IVDD 29, Non-IVDD 180
- 2011: IVDD 209, Non-IVDD 75
- 2012: IVDD 215, Non-IVDD 76

Legend: IVDD in blue, Non-IVDD in purple.
Number of NCARs that are related to IVDDs

- IVDD: 477 (19.6%)
- Non-IVDD: 1960 (80.4%)