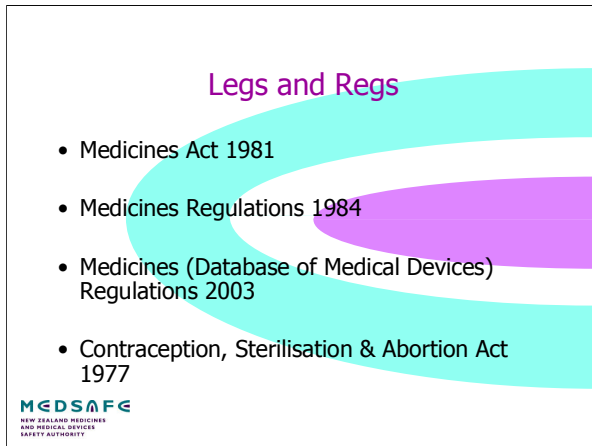


Thank you for this opportunity to address medical device corrective actions as part of this conference. To be able to discuss this subject with both the suppliers and the customers who may be affected by such actions is quite a unique opportunity. I have endeavoured to address aspects that affect both parties as well as clarifying Medsafe's role in the proceedings so that everyone has an understanding of their role in a corrective action.

There is one myth I would like to bust straight away is that recalls are bad things and regulators take a dim view of them. Nothing could be further from the truth.

Corrective actions – a term to encompass all potential actions including recalls, alerts, etc – are the sign of a functioning quality system. In most cases they indicate that manufacturers are listening to feedback about their products and recognising that sometimes things go wrong impacting on patient safety. The alternative to this is ignoring a problem and continuing to supply a product regardless of the dangers it poses to patient safety. Therefore corrective actions should not be viewed as annoyances or difficulties but as improvements to patient safety.

I will begin with a brief recap of the legislation and regulation that covers medical devices.



There are two Acts and two sets of Regulations that have direct affect on medical devices in New Zealand. These are;

- The Medicines Act 1981
- The Medicines Regulations 1984
- The Medicines (Database of Medical Devices) Regulations 2003
- The Contraception, Sterilisation and Abortion Act 1977

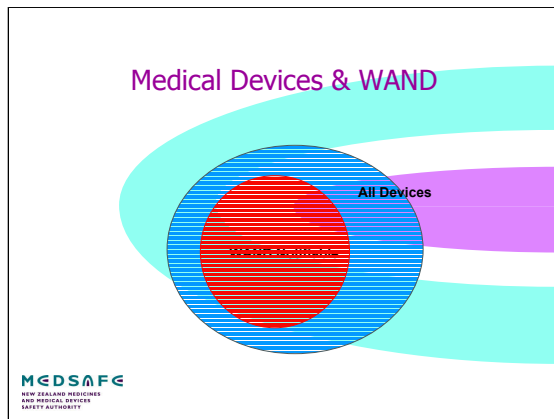
You may be surprised to see the last item on this list. However it requires the Minister of Health to set standards for condoms supplied in New Zealand, and also sets out penalties for non-compliance with these standards. Condoms are deemed to be medical devices so compliance with the Contraception, Sterilisation and Abortion Act 1977 is additional to the requirements of the Medicines Act and its regulations. If you are importing, or considering importing condoms, please refer to this legislation before doing so.

The Medicines Act 1981 provides New Zealand with the legal definition of a medical device. This definition is somewhat unique and is not aligned with the definitions used by other countries, such as Australia. For example, a pregnancy test kit is specifically defined in the Act as a medicine. Likewise products including saline for irrigation, bone cements with antibiotics and IUDs are all medicines in this country. If you have any concerns about whether a product is deemed a medical device in New Zealand, check the legislation and then with Medsafe. All New Zealand statutes and regulations are available on line at [www.legislation.govt.nz](http://www.legislation.govt.nz).

People often say that our medical device legislation is weak and has no measures to deal with problem devices. This is not true. Section 38 of the Act provides a definition of an unsafe medical device, and gives the Director General of Health the power to investigate medical devices that they deem to be unsafe. It also details specific response times for the supplier of devices. Section 37 of the Act grants the Minister of Health the power to prevent the supply of a medical device for any reason for a period of up to 12 months.

Medsafe is not toothless.

Our only medical device specific regulation is the Medicines (Database of Medical Devices) Regulations 2003. These established the Web Assisted Notification of Devices, or WAND, database. It is a requirement under these regulations that any device that is not exempted under Schedule 1 of the regulations is notified to the database within 30 working days of it becoming available on the New Zealand market.



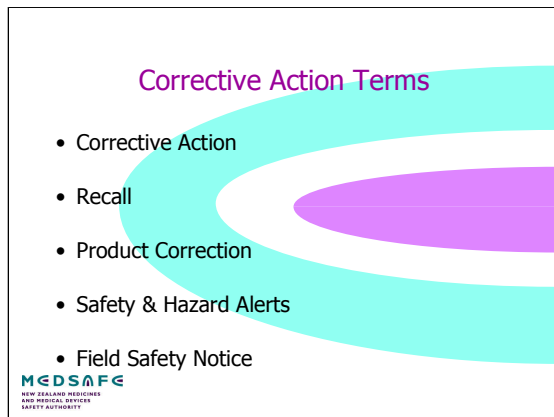
Now here is an important point. The WAND regulations have exemptions; the Medicines Act doesn't. Therefore medical devices that are exempted from notification to the WAND database are still medical devices, and must comply with all the other requirements of the Act and regulations. So, those of you who are supplying invitro diagnostic, or IVD, equipment are still supplying medical devices and must comply with the Medicines Act 1981 regardless of whether these devices are notified to WAND or not.

Remember it is the Medicines Act 1981 that defines a medical device, not the Medicines (Database of Medical Devices) Regulations 2003. These regulations define which medical devices need to be notified to WAND.

I also mentioned the Medicines Regulations 1984. These regulations define the labelling and advertising requirements for medical devices. As the labelling requirement is that the device be labelled with either the name of the manufacturer or the name of the New Zealand supplier most devices should be compliant. The regulations also require suppliers of equipment that operate using magnetic, galvanic, electrical, radiation or vibratory forces to quantify these forces and to demonstrate the device has the properties claimed.

Of course, all electrical medical devices must also comply with the necessary electrical regulations as well as the above.

That is a thumbnail sketch of the New Zealand legislative scene as it relates to medical devices. Before I go any further I will explain some of the terminology that surrounds corrective actions so that we are all working from the same understanding.



I'll start with Corrective Action. This is the blanket term used by Medsafe, and many other regulators, to refer to any and all actions taken by a supplier with respect to correcting or mitigating a safety problem with a medical device. The term covers a wide range of actions including; recalls, product corrections, safety alerts, hazard alerts, notifications and advisories.

But what do these individual terms mean?

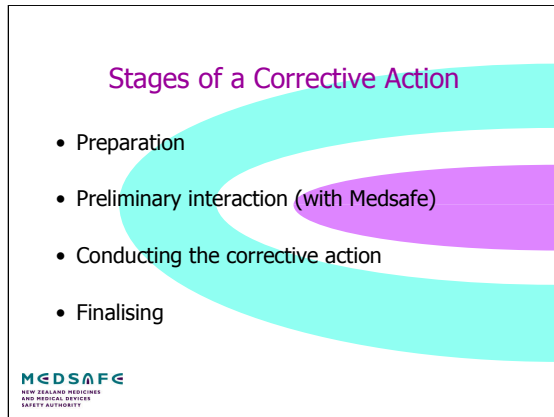
**Recall.** This is a word that strikes fear into many manufacturers' and suppliers' hearts, but it shouldn't. Granted, the US FDA calls any action to be taken by a supplier, whether it involves retrieving stock or not, a recall. In New Zealand a recall generally means the removal from supply of a defined sub-set of a particular product. Removal of supply can occur to consumer level, retail/hospital level, or wholesale level. It can include collecting product from end users or instructing them to destroy or dispose of them.

A Product Correction is the upgrading of device by means of changes to its mechanical or electronic operation, the software or firmware that controls the device, or the instructions for use.

There are two types of Alerts that are commonly issued; a safety alert and a hazard alert. The purpose of the two is the same and that is to alert the users to a particular set of circumstances that may occur and what can be done to mitigate or manage the situation should it occur. The difference between them is that a Hazard Alert is issued for an implantable device, such as a prosthetic joint, stent, breast implant, cochlear implant or cardiac pacemaker or defibrillator. A Safety Alert is issued for non-implantable devices.

Another term that is becoming increasingly common from European manufacturers is a Field Safety Notice. This is the blanket term used in EU nations and replaces the terms recall, corrective action and alert. It is not used here in New Zealand.

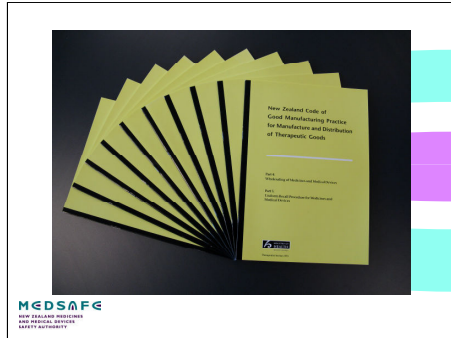
The legislation gives us the lie of the land; the terminology our language. Now we can look at the process of conducting a corrective action.



Broadly speaking there are four stages in the conduct of a corrective action. These are;

- Preparation
- Preliminary interaction with Medsafe
- Conducting the corrective action
- Finalising the corrective action

With the exception of preparation, each of these stages will involve at least one other party – Medsafe. Most will also involve customers, be they hospitals or other end users. Each party has a role in the process and each party must successfully complete their role for the situation to be resolved.



For suppliers of therapeutic products the Ministry of Health has issued a code to good manufacturing practice, or GMP. This code comes in five volumes of which volume 5, the Uniform Recall Procedure for Medicines and Medical Devices, should be your bible. As this is a mouthful of a name I will refer to it as the URP during this presentation. If you do not have a copy, or would like to obtain an extra copy of this code, contact me to arrange for a copy to be sent to you.

No one plans on having to conduct a corrective action; they happen in response to events. So it is best to be prepared for such an eventuality – both as a supplier and as a customer. Preparedness takes two forms; knowing what to do, and having information available.

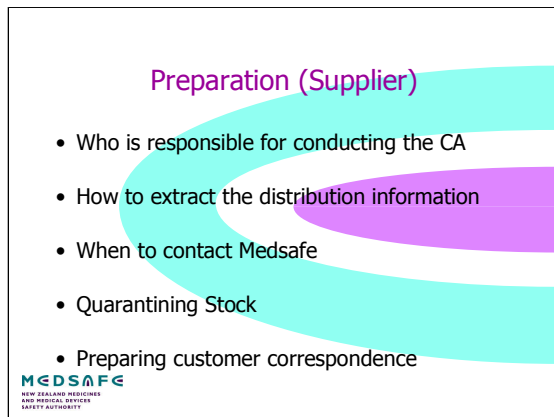
But what information?



The key information is what products you have and where they have gone. For a supplier this means having records to batch or lot number level, serial numbers, and software version numbers of product supplied along with who they were supplied to and when. For a customer it means the same thing. One of the biggest impediments to conducting a successful corrective action is not knowing where product is. Remember though, a corrective action can occur years after a product is supplied. This may not be significant for rubber gloves, but it will be for a reusable medical device. Using infusion pumps as an example, as a supplier do you have sufficient records that allow you to definitively know who you supplied particular serial numbers of devices to five years ago? If you took over the agency two years ago do you have the serial number records from the previous supplier? In hospitals do you have records of all serial numbers of devices currently in use – and of those withdrawn from use? It is a lack of these records that often prolongs a corrective action for months.

Recently Medsafe has been contacted by a manufacturer who conducted a worldwide corrective action in 2002. Six years later they still cannot account for several units of the device. They have supplied serial numbers to their distributors and the regulators and need to account for these devices even though they may no longer be in operation. While an extreme case, it is not unusual for a supplier to advise us that they can account for all but a small number of devices because either they or their customers do not have sufficient records to locate the devices.

The take away message is ensure you have a means of recording the distribution of all medical devices to an identifiable level and you can recall information easily.



That's one part of your preparation. The other part is knowing what to do if you need to conduct a product correction. For suppliers Chapter 2 of the URP provides guidelines on what needs to be done. This includes;

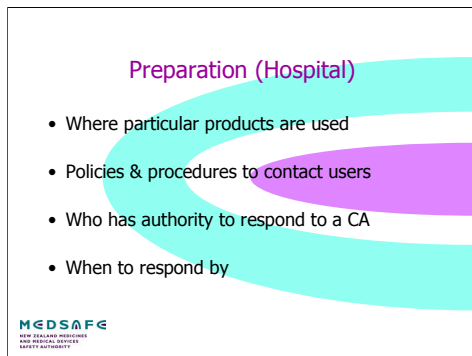
- Determining who is responsible for conducting a corrective action
- Knowing how to extract the distribution information from your records
- When to contact Medsafe
- Quarantining stock
- How to prepare a product correction letter and acknowledgement form

That brings us to another consideration which is the type of records that may need to be kept as a result of the corrective action, and how they are kept. For example, if it is a recall action it may be advantageous to keep records confirming the destruction of product for the accountants and auditors as well as Medsafe.

A recent corrective action had to be partially repeated as the records were kept in email files that were deleted when the person coordinating the action left the company. With no hard copies there was no proof of the actions. The only option was for the supplier to go back to their customers and request the confirmations a second time.

I recommend that if you do not already have a plan for conducting a product correction that you spend some time preparing one. It is a valuable exercise in crisis management and means that should something like this occur when a key person is away on a business trip or on leave that there is a procedure that staff can follow.

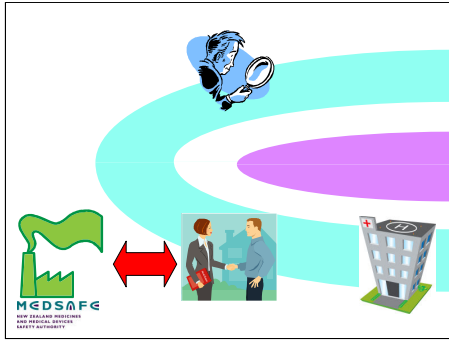
But don't just plan it – test it. The plan might look good on paper but might not work. The quarantining of product can be problematic. There have been instances of product being returned as part of a recall not being quarantined properly with the result that the returned goods were then dispatched again, greatly prolonging the corrective action.



In the hospital environment it means establishing and knowing;

- where particular products have been supplied to or are being used within the organisation
- policies and procedures in place to contact users of the equipment
- who has the responsibility and authority to respond to a corrective action
- when to respond by

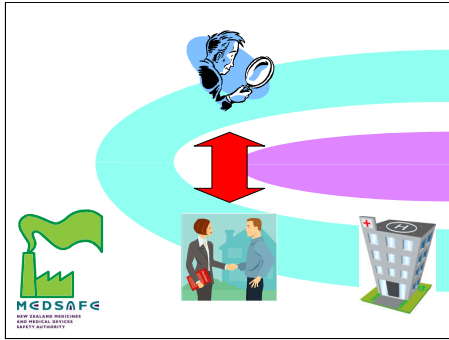
Follow the Boy Scout motto – always be prepared!



To illustrate a sequence of events. The manufacturer contacts their distributor to advise them of a problem with the software that controls an infusion pump. The correspondence details the model of pump and version number of the software, the dates they were manufactured, and a list of affected serial numbers supplied to the distributor. A quick check confirms that the distributor has supplied 50 units to 8 customers, has 7 on the shelf and uses three as loan units.

The next thing to do is to advise Medsafe. We need to be sure that whatever action you intend taking is appropriate and is conducted appropriately.

You also need to quarantine the stock on the shelves, and locate and quarantine the loaner units. From your distribution records you should prepare a list of the affected units that have been supplied.



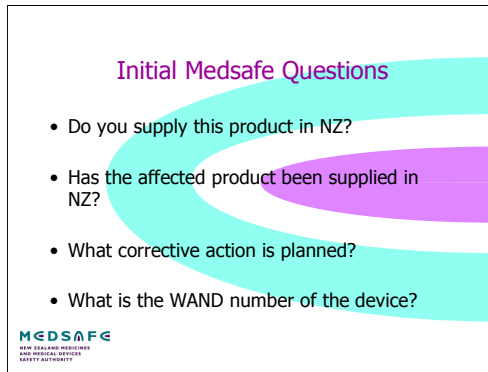
Medsafe learns about corrective actions from many different sources, but primarily through two; direct contact with the supplier, and from other regulators. The UK MHRA, US FDA and Health Canada all provide public information about corrective actions occurring in their countries. The TGA advises Medsafe, along with all the Australian state and territory health safety officers, of most corrective actions in Australia. It is for this reason that companies occasionally receive correspondence from Medsafe asking about corrective actions taking place in other parts of the world.

However Medsafe prefers to hear about these actions promptly and directly from the suppliers.

The URP states that all recalls must be carried out with the knowledge and consent of the Ministry of Health. So if you are aware of any corrective action, or potential corrective action, you should immediately contact Medsafe to discuss the situation.

As I said previously the purpose of contacting Medsafe is to ensure that the action being taken is appropriate and that the corrective action is conducted appropriately.

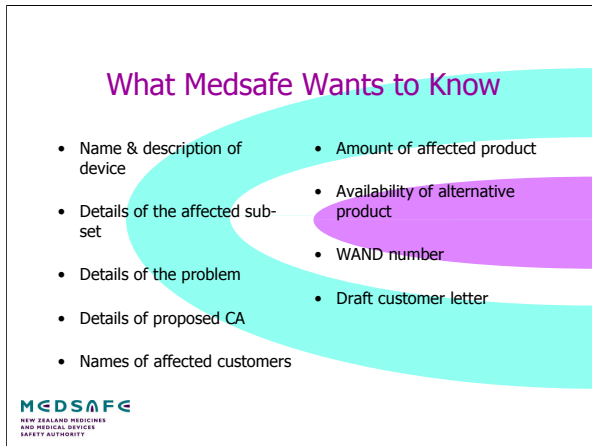
Remember a corrective action is the usually result of a functioning quality program. It is happening to improve the safety of a device. It is not a black mark against a supplier or manufacturer. Personally, I am more worried about the companies that have not been in contact with Medsafe than those that I am in regular contact with. The companies I am dealing with several times a year have processes and procedures in place – and are using them – to deal with safety issues. I cannot be so sure about companies that may be conducting corrective actions without involving Medsafe.



This is why Medsafe uses the international information to find out if products have been supplied in New Zealand. The correspondence will outline the details known about the device and the problem and will request responses to four questions;

- Do you supply this product in New Zealand?
- Has any of the affected product been supplied in New Zealand?
- If so, what corrective action is planned?
- What is the WAND number for the device?

A response to these questions is requested as soon as possible but within 5 working days.



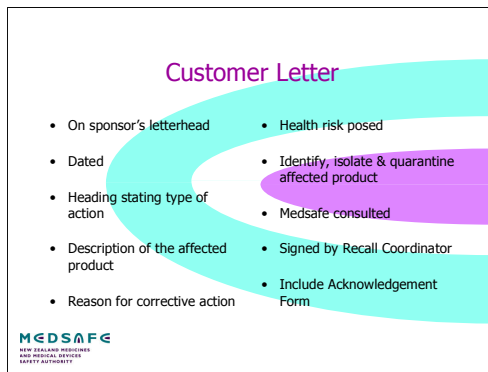
Whether it is in response to the above request or the initial information being supplied to Medsafe the base level of information, as indicated in Chapter 3 of the URP, should be as follows;

- The name and description of the device
- Details of the affected sub-set of product; lot number, serial number range, date of manufacture, software version number, etc
- Details of the problem
- Details of the proposed corrective action
- The names of the affected customers
- The amount of affected product supplied
- The availability of alternative supplies
- The WAND number of the device, if notified to WAND
- A draft customer letter advising them of the situation and how it will be resolved

From this Medsafe determines whether the proposed action is appropriate to the risk posed by the problem. Often the draft customer letter requires reformatting and additional information may be requested.

Note that it is the responsibility of the sponsors to advise their customers of any corrective actions. Medsafe needs to be advised and involved in the process, but advising the customers is the sponsor's job. After all you know who your customers are.

Suppliers please don't assume that a letter used in the USA or Europe or Australia will be acceptable here because it may not be. For this reason when supplying a letter to Medsafe for review it is best to send us a document in an editable format, like a Word document, rather than an Acrobat file. It is easier and clearer if I can annotate a document instead of providing you with a long list of changes to be made.



Chapter 4 of the URP details the following requirements for the customer letter;

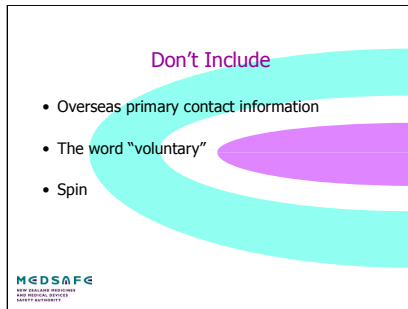
- To be on the sponsor's letterhead
- To be dated
- To have a heading as to the type of action being taken
- A description of the product and affected sub-set
- A reason for the corrective action
- A statement of the health risk posed by the problem
- Clear instructions for the customer to follow to deal with the problem
- If required, state the need to identify, isolate and quarantine affected product
- If required, describe how the affected product is to be returned
- State that Medsafe has been consulted
- Be signed by the Recall Coordinator or a senior member of the company management team
- Include an acknowledgement form for the customer to complete and return
- Contact details for further information

Importantly any response required of a customer should be to a local New Zealand address, phone or fax, or to a free-call phone or fax number. Letters requiring responses to Australia or elsewhere are unacceptable. Refer to 4.2(f) of the URP, which states, "Provide a means by which the form may be returned free of charge". While not free, a local fax transmission is acceptable.

Sometimes it is necessary to include the contact details of a product specialist who may be located overseas. This is acceptable but only as a secondary contact. New Zealand contact information must be given as primary contact.



This is because Medsafe expects every corrective action to include an acknowledgement form for the customer to complete and return. Again Chapter 4 provides guidelines on the contents. This forms a key part of the supplier's corrective action file as it shows that the customer has received the information and advised whether they are affected or not. It is vital that these forms are both included by the supplier and completed by the customers. Medsafe may use this information to review the performance of the corrective action.

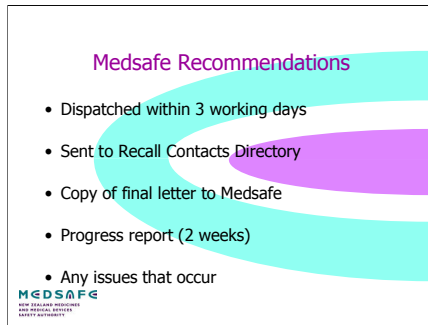


In addition to no overseas contact details other don'ts include;

Use of the term "voluntary". This is used in the United States to indicate that the manufacturer has initiated the action rather than required by the FDA.

Unfortunately this term has been misinterpreted in the past by some customers as meaning that compliance with the requested action is voluntary on their part. To avoid the potential for confusion voluntary should be removed from the correspondence.

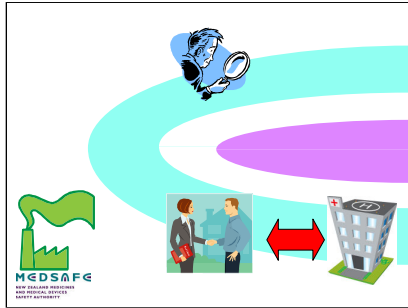
Don't include spin. The object of the exercise is to tell customers of a real or potential safety issue and what to do. The message should be clear and concise. It should not include extra communication designed to promote the company or public relations spin. Last week I was sent a draft letter advising customers of a "quality focused safety enhancement available to them at no charge". I like humour, but not in corrective action letters.



Once Medsafe has reviewed the letter and all recommended changes made the supplier will be advised that they may distribute the letter to the affected customers and includes the following comments;

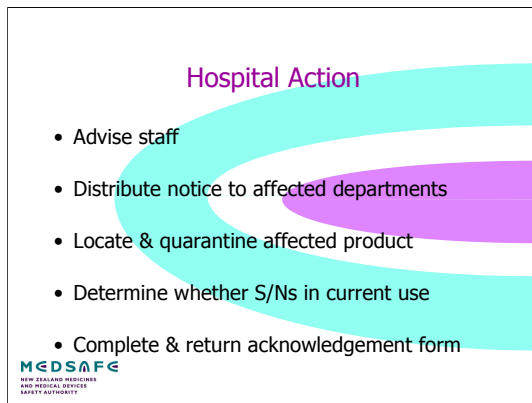
- The letter should be dispatched as soon as possible but within 3 working days of the go ahead being given by Medsafe
- Letters being sent to hospitals should be sent to the contacts detailed in the Medical Device Recall Contacts Directory compiled by Medsafe
- A copy of the final letter should be supplied to Medsafe for its files. (Note, just one copy of one letter is needed. Medsafe does not need a copy of each letter sent.)
- A progress report on the corrective action is expected by a specified date which is approximately two weeks after the letters have been dispatched
- That Medsafe should be contacted immediately should there be any issues develop that impact on the conduct of the corrective action





With the action agreed to, the communication ready for distribution, and the list of appropriate contacts, the supplier distributes the information to the affected customers.

On receipt of a corrective action notice hospitals need to assess the information they have been provided and determine the extent that it impacts on them. This may include



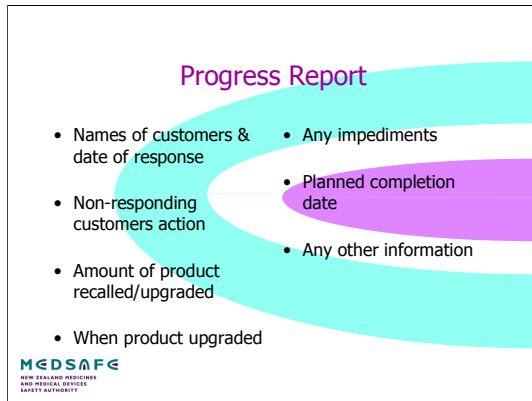
- Distributing the notice to all departments where the affected device is used
- Advising staff including Risk Managers, CEO's, Heads of Department, Biomedical Engineers, the Chief Medical Officer
- Locating and quarantining affected product
- Determining whether all affected serial numbers are in current use
- Importantly it also includes completing and returning the acknowledgement form to the supplier as soon as possible.

The acknowledgement form is a key document in the corrective action paper trail. Medsafe expects a 100% response rate with all customers completing and returning the form even though not all hospitals contacted may be affected by the corrective action.

At this point the corrective action is between the supplier and their customers. Medsafe now takes an observer role and monitors the progress of the action.

If an organisation receives a notice of a corrective action and is unsure if Medsafe is aware of the action, please contact us.

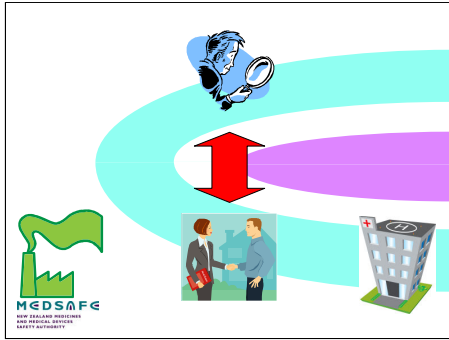
Medsafe expects suppliers to make every reasonable effort to contact their customers and obtain a completed acknowledgement. The minimum expectation is that three attempts will be made to obtain this information. Every attempt needs to be documented, whether it is a fax, phone call or email. If after three attempts there has been no response the supplier should contact Medsafe to discuss the situation.



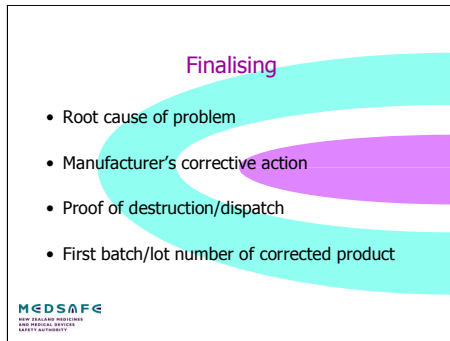
About two weeks after the corrective action is initiated Medsafe requests a progress report. This report should include;

- The names of the affected customers and their date of response
- Details of what action is being taken to follow up on customers that have not yet responded
- If a recall, how much product has been returned
- If a corrective action, how many devices have been upgraded and when
- Whether there have been any impediments to the conduct of the corrective action
- The anticipated completion date for the corrective action
- Any other information that is relevant about the conduct of the corrective action
- If the action has not been completed by this time then a further report is requested for four weeks time updating progress.

Depending on the nature of the corrective action it may be several months before it is completed. Returning to our infusion pump example, the problem may have been detected but new software may need to be developed to address the issue. During this time the sponsor should provide a “work around” or additional safety instructions until the new software is available. In most cases software will need to undergo a three-month period of validation and verification before it can be supplied to customers. If the first version of the software fix doesn’t work then it is back to the beginning and the three-month clock starts again. In this case the supplier may also need to communicate with the customer as well as Medsafe on a regular basis to update them on developments. Once the upgrade becomes available it may take two or three months to install all the upgrades due to the clinical availability of the device. During this time Medsafe will expect monthly progress reports.

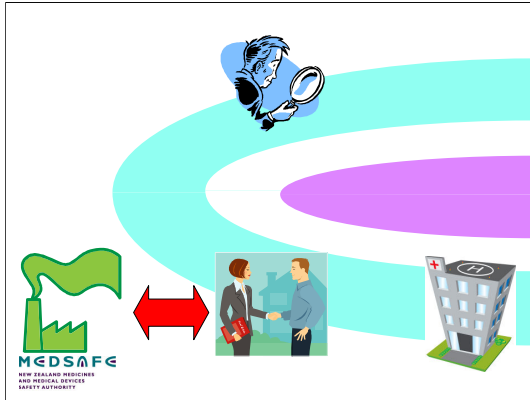


Once a corrective action has been completed it is necessary for a final report to be submitted by the sponsor. This report is more than just a note to Medsafe to say that they have completed the action. In addition to the information requested in the progress reports Medsafe should also be advised of;



- The root cause of the problem
- Action taken by the manufacturer to prevent a reoccurrence of the problem
- If goods have been recalled and destroyed locally proof of destruction will be requested. This can be in the form of a destruction certificate provided by a landfill operator.
- If goods are being returned to the manufacturer copies of the airway bill and the commercial invoice should be supplied
- If modified product is being supplied, the batch number of the first corrected batch should be advised

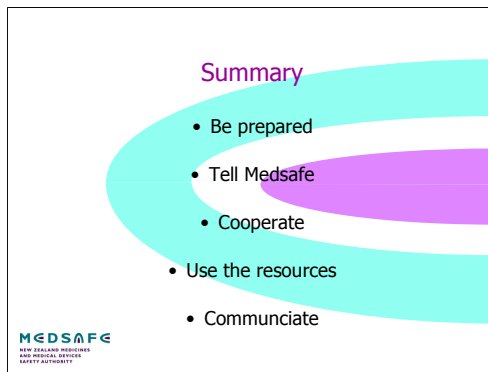
Medsafe will only close a file once it is satisfied that the root cause has been investigated, the issue has been adequately resolved, and that it should not reoccur. Only then will Medsafe advise the supplier that the matter is closed.



Once the corrective action is closed the supplier can then also report back to their manufacturer on the action taken and that Medsafe is satisfied with the result. Many manufacturers need to report back to their notified bodies and home regulators that the action has been completed worldwide before these organisations will close their files on the situation.

At Medsafe each corrective action file is peer reviewed to ensure that all facets have been addressed. Occasionally it is necessary for Medsafe to contact the supplier to clarify an issue before the file is properly closed.

Medsafe maintains a filing system of all corrective actions it has been involved in. Sometimes it may be necessary to reopen a file at a later date due to an expansion of the original action, or a subsequent action may link to an earlier action. Fortunately most corrective actions remain closed.



This presentation has covered the basics of a typical corrective action. Due to the wide variety of technology used in medical devices today there can be many variations on this pattern. However the summary of basics when conducting a corrective action are;

- Be prepared – get a copy of the URP, familiarise yourself with it, and have a procedure for dealing with a corrective action before you need to use it
- Tell Medsafe – let us know as soon as you are advised of a potential corrective action even if it doesn't affect New Zealand
- Cooperate – Medsafe wants to see all corrective actions being conducted promptly and successfully for all parties. We can provide the experience and guidance you need to achieve this.
- Use the resources – among these are the URP and the Medical Device Recall Contacts Directory
- Communicate – make sure you keep your supplier, Medsafe, and your customers apprised of developments and progress

I hope that this has helped to clarify the corrective action process for both suppliers and hospitals. Like with most things, the key is communication. A failure to communicate is going to potentially take more effort and resources to resolve than the original issue, so it pays to be up front.



### **Can I just phone and tell customers about a problem?**

If it is an urgent issue Medsafe does not object to suppliers contacting their customers by telephone to advise them to quarantine a product. But the initial telephone contact needs to be followed up within 3 to 5 days with written confirmation to the customer.

### **Why do I have to write? Can't I just send an email?**

While emails are increasingly used as the prime means of communication they do not provide a valid audit trail proving that you have contacted the customer. Emails can go astray; people don't have their out of office on; incorrectly addressed don't always bounce back. For speed and verification the best method is to fax.

### **I've been advised of a corrective action but we don't have any of the affected products in New Zealand. Do I need to tell Medsafe?**

Medsafe recommends that if the affected product is normally available in New Zealand that you advise us of the corrective action and that no affected product is in the country. As we monitor corrective actions in other countries we may find out about the matter from another source and contact you requesting information anyway. Many suppliers send us advisories of overseas actions. So if you are aware of a corrective action let us know.

### **I have received a recall notice that doesn't mention Medsafe, doesn't have an acknowledgement form, or is asking me to contact the USA. What do I do?**

Send a copy of the notice to Medsafe for us to follow up. Hopefully you will be able to identify the local supplier that sent the notice. Contact them and ask them for the correct information.

### **We market a device in both Australia and New Zealand. Do we have to tell Medsafe of any issues?**

Yes. The TGA is responsible for the Australian market only. Medsafe is responsible for the New Zealand market. Both regulators need to be contacted separately and their respective requirements met.



**Our hospital imports devices only for use in our organisation. Do we have to tell Medsafe of any issues?**

Yes. By importing a device you are the sponsor of the device and you are responsible for the safety of the product and those using it. If you are aware of an issue you need to advise Medsafe of the issue and the steps taken to address it.

**We received a recall notice from the manufacturer for a product that we have in our warehouse but haven't sold to anyone. What to we do?**

The only thing you don't have to do is contact the customers, because there are none. In every other respect you still need to advise Medsafe and do the usual things. You still need to quarantine the stock so it won't be supplied. If you need to destroy it locally you will have to provide a destruction certificate.

**We are releasing a software upgrade for a programmer because we have new models coming and they communicate differently with the device. Is this a corrective action?**

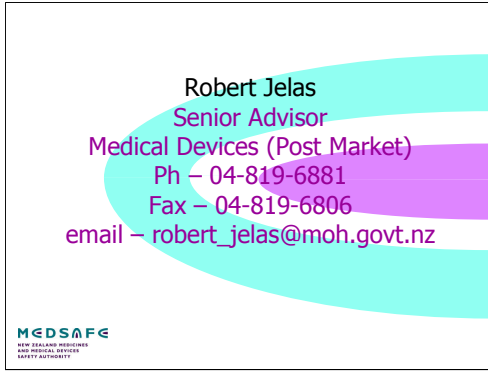
No. Adding new features to a device to increase functionality rather than to address a safety concern is not a product correction and does not need to be advised to Medsafe.

**The manufacturer of a device wants us to send a letter to all the doctors using our product to remind them about a warning in the instruction manual. Is this a corrective action?**

Yes. The manufacture has had concerns about incidents reported to them relating to the use of the device and has decided to issue a warning. This is a corrective action and needs to be communicated in consultation with Medsafe.

**Instead of an acknowledgement form will Medsafe accept a proof of delivery that the corrective action letter was sent?**

No. Proof of deliveries show that the correspondence was delivered; it doesn't show that anyone has read it or done what has been requested. Acknowledgement forms are therefore required.



If anyone has any other questions about the process please feel free to ask away now or to contact me at Medsafe at any time.