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Toolbox for the **"Responsible Facility Authority"** for medical gases

Mark Allen, ASSE 6050 and Keith Ligi,
ASSE 6010, 6020, 6030 and 6040

Notes on this **pamphlet**

In the 2021 NFPA 99 Healthcare Facilities Code, a newly invigorated Responsible Facility Authority for medical gases will please some and concern many. This pamphlet is presented as a service to the healthcare community to help scope and actualize the six major deliverables that NFPA has placed under this responsiblity. This document should only be used in conjuction with the NFPA 99 Healthcare Facilities Code, from which most of the essential requirements here derive. All references to NFPA are to the NFPA 99 2021 version.

About the **authors**

Mark Allen has been involved in piped medical gases through his entire 40+ year career. Beginning as a verifier before that was even a term people used, he has been involved in verification, marketing, education, and standards development, and is the author of numerous articles, educational papers, and design guides for medical gases.

Keith Ligi started his 20 year medical gas career as an installer and is currently the RFA for one of the largest healthcare systems in the United States. Working hand in hand with engineers and architects, contractors, testing agencies, clinical staff and finally in-house maintenance, he assures medical gas systems are designed, installed/tested and maintained at a minimum to the requirements of NFPA 99.

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Contents

Do you need an RFA?

Guidance for facility administration

In the NFPA 99, 2021 "Healthcare Facilities Code" there is a new emphasis on a "Responsible Facility Authority" for medical gases. It may be a surprise, but the role involved is not altogether new. The "responsible facility authority" appears first in the 1993 edition of the standard. That person was named at the time to receive, evaluate and approve the test reports after work was done on any medical gas system.

While the role is there, the sense one has is of a simple 'straw man' set up because the logical sequence of installation and testing operations needed an end point and a bridge from the contractor to the facility. The standard gave no definition on who this "RFA" might be, what qualification they should have, or how they were to be chosen.

That role did not evolve, but the Code did. There are very substantial differences between the 1993 and 2021 versions of the standard. It can beseen how the code has focused on various concerns through its evolution, driven by where the most common, difficult or spectacular problems were perceived (and often demonstrated) to exist.

But throughout, NFPA has kept focus on keeping the standard flexible. If a technology or technique can do the job and attain the desired ultimate result, the view is that the standard should not be a barrier. A facility should be enabled to do its job in any way which is consistent with the overall goals of patient safety.

The result is to leave a facility with a lot of options. That means decisions to make and an increasingly complex set of technologies and potential solutions to choose from.

A parallel thread is that the Code has dealt extensively with the problems found in construction, and now those parts of the code see little change from edition to edition. What then becomes much more visible from incident reports are problems from inadequate maintenance and inept operation. The code will always be limited in how much it can do with this, given the bewildering variety of legacy systems involved. Risk analysis, resource allocation and considered case-specific judgment is required. If those are well done, the medical gas systems will operate successfully, economically and safely within a wide band of technologies and designs. If they are not done or are done badly, the same problems will occur over and over and no progress can be made.

Taken together, ensuring desirable flexibility while accounting for confusing legacy systems define a challenge: who is going to take the necessary decisions? Do they have the knowledge they need and do they appreciate what the code is seeking to ensure in patient safety?

NFPA has since 2005 mandated various plans and programs for the operation of these systems. They include at least:

- Inventory of equipment,
- Inspection plans and processes to be used,
- Maintenance programs and procedures,
- Emergency planning,
- Construction process control as it affects the medical gases.

In 2021, an additional requirement is added to these: a requirement to institute a Permit to Work system, which is intended to ensure that any work on medical gases is done smoothly, by qualified individuals and with the full understanding and cooperation of the entire facility staff.

The implication back in 1993 was that there was someone at the facility competent in medical gases, conversant with the code, and with the necessary authority to approve the use of these systems on patients. In the 2021 revision, that person, that knowledge and that authority is no longer implied. The simple 'straw man' of the 1993 standard, like the scarecrow in the Wizard of Oz, will now be required to demonstrate he has a brain.

NFPA 99 2021

> *5.1.14.1.2.1 The Responsible Facility Authority shall have primary responsibility for implementation of the piped medical gas and vacuum system requirements of this code for the Health Care Facility, including all medical gas, medical support gas, medical vacuum and WAGD systems.*
>
> *...*
>
> *5.1.14.1.3.1 The person designated as the Responsible Facility Authority shall be qualified to interpret, implement and advise on this Code."*

As a practical matter, is the RFA someone who needs to be appointed NOW? The NFPA 99, 2021 after all will probably require at least 5 years to come into effect in most jurisdictions, and much longer in many (although as always some will move earlier and the exact effective date in any specific jurisdiction is unpredictable). Accreditation agencies will generally enforce the rules in effect in the local jurisdiction. Since no earlier edition of the code places any particular requirements on this person, there is no reason it can't continue to just be whoever, case by case, as it has been since 1993. Right?

There is of course an argument for delaying the appointment until the rules come into force. Creating a new role is always fraught with questions of selection, compensation, and hierarchy. This one is particularly challenging as it has never existed before and there is little collective wisdom to draw on for comparison.

Which is not the same as saying there is none. Several larger systems and facilities have had individuals working in this role over many years, (although none of course have carried this title). Their experience - notably the state of their medical gas systems when compared to systems and facilities where there is no single individual coordinating the program, is highly instructive. As one would expect, it confirms that focus brings results.

If you are a multi-facility system, do you need an individual RFA for every facility? No, there is nothing in NFPA which prohibits having one RFA shared across a healthcare system. Nor is there any prohibition on using outside contractors for the purpose. Any administrator of experience will understand there are tradeoffs in this: the better the person knows the facility, and the more engaged they are, the more effective they will be. Inevitably, an RFA shared across multiple facilities will be otherwise occupied when needed, which can cause delays and frustration. So consideration should be given to having an RFA or a deputy in each major facility at least.

Who would be a good appointee? The role demands three general skills:

1. **Knowledge of the systems.** This includes their operation and as many of their peculiarities and flaws as possible.
2. **Knowledge of the norms.** That includes the 99 Code of course, but equally it involves the internal processes and procedures that the facility uses on a routine basis.
3. **Diplomacy.** The role requires frequent contact with other facilities staff at all levels, medical staff, administration, "Authorities Having Jurisdiction" like the health department, fire department, city, county and state people, CMS / JCAHO / DNV / AAAHC accreditation surveyors, suppliers, architects, consulting engineers and contractors at many levels. This person will be required to square many circles and that will require a better than average talent for tact and negotiation.

Just Chatting: The RFA and the AHJ

The interaction between the AHJ (Authority Having Jurisdiction) and the RFA (Responsible Facility Authority) will be an important challenge for facility administration.

The RFA i s now assigned responsibility for medical gases in a specific facility and for having knowledge of the Code. They are also explicitly assigned responsibility for interpretation of the Code.

On the other hand, the AHJ is of course the agency, usually associated with a government, who NFPA assigns the primary responsibility for decisions regarding "threats to life". Clearly between them there is overlap and risk of conflict.

AHJ's are generalists and rarely have very deep knowledge of medical gas issues. The RFA is of course expected to be the opposite - a specialist with deep knowledge of their particular facility and of the Codes involved. Yet AHJ's are often jealous of their prerogatives, and they don't always yield gracefully, faced with superior knowledge or not.

The wise RFA should be encouraged to develop and always cultivate a close working relationship with their opposite numbers at the AHJ. Avoid conflict - there is no winner once the fire gets lit.

Most facilities who have undertaken in the past to establish this function have selected a mid level supervisor with the relevant experience. An experienced supervisor or top mechanic from the plumbing department would be typical. The individual chosen should have an interest in the subject, good experience of the facility and it's quirks, and a pleasant, cooperative personality. The most successful also share the ability to stand their ground in an argument without becoming ugly.

The NFPA is very open about the formal qualifications permitted for this person. Any qualification following the ASSE 6000 "Professional Qualifications Standard for Medical Gas Systems", outside of the 6005 Generalist, 6050 Instructor or 6060 Designer is accounted acceptable. This is arguably too wide an allowance, but it means the decision can focus more on the quality of the person than on the credential they hold. Undoubtedly there are highly skilled persons in facilities who would be ideal but do not hold any of these credentials. The credential should not be viewed as an obstacle to getting the right person, as the right person can readily obtain the credential.

No facility or even large healthcare system we are aware of has the internal resource to formally train someone for this position, albeit such internal training is also permitted as a qualification, if it did exist.

Whether or not you already have anyone appropriate credentialed to one of these, the 6040 Maintenance Personnel qualification is clearly the most relevant, and it is recommended your candidate pursue that qualification (even if they hold another on the list). The 6040 course, well taught, will provide the essential background on the Code, which they will be challenged to get any other way. No 6040 course however can prepare your candidate for the practical side of the role. That seasoning must be acquired on the job, and is why an experienced practical mechanic with the capability to supervise would generally be a preferred choice.

The position should report to the C-suite facilities manager or their immediate deputy and thereby be at least approximately equivalent to other supervisors in the maintenance or facilities department.

Along with choosing the person, the task before your RFA needs to be defined. The first question is: how far do you want to take this? NFPA of course only considers the maintenance and operation of the piped systems, and particularly concerns itself with the construction of those. But poor cylinder inventory management has stung many facilities with a big bill because they could not account for the tanks. Could the RFA be assigned to manage that? Do you want them to manage the people who physically move cylinders to and from the floors? Do you want them to manage purchase of the gases? Naturally, these are answers each facility will make on their own, but it is essential to scope the role right up front, not least because it means allocating resources to effectively handle the job you define.

Remember that scoping the role too widely will make it more difficult to perform, more difficult to fill and more problematic when it falls vacant. The broader the scope, the more need for others assigned to assist, which will also elevate the role toward administration. That is not the intent of the role as NFPA 99 lays it out, so think carefully about the mission you will assign.

Of course, a great deal of this will come down to what is already in place. In a facility with a robust medical gas management program already in operation, the initial task may be only a review with realignments as needed. Possibly, training and credentials for the RFA will be required. On the other hand, in a facility which starts with little by way of procedures or documentation, there will be a lot to do and you can expect some unpleasant revelations until the processes are up, running and smooth.

In all facilities the essential first requirement is an accurate inventory of all the medical gas equipment. This inventory will be essential to understanding what policies to create, and is important when inspection and maintenance procedures come to be outlined and performance of those processes recorded.

With that inventory in hand, the RFA should be managing at least these mandatory policies for that equipment:

- Inspection plans and processes, (see chapter 4 in this Toolbox)
- Maintenance programs and procedures, (see chapter 5 in this Toolbox)

The RFA will require IT and possibly CFO support to accomplish this in a way that will ensure this inventory will relate to general asset management and the balance sheet and that it is usable by all interested parties.

- There are then three planning and control processes that the RFA will need to help create and manage:
- Emergency planning as it involves medical gases (see chapter 6 in this Toolbox)
- Construction process control as it affects the medical gases (see chapter 8 in this Toolbox)
- The "Permit to Work" system for the medical gases (see chapter 7 in this Toolbox)

What already exists in your program should be assembled into a coherent body along this outline. Then, any procedures and documentation that does not exist will need to be created.

As administration of course you always remain

responsible, so development of a governance procedure will also be essential. While this may include contributions from your RFA, it will rarely be written by them. We describe in Annex I to this booklet a governance system drawn from the U.K. HTM 02-01 standard (the U.K. has mandated this role under their title of "Authorized Person" since 2006). As you will see there, the HTM 02-01 establishes a Medical Gas Committee whose role is to oversee the various aspects of the medical gas management program. While the last thing the average healthcare facility needs is another committee, this may be an idea worth taking up as a way to oversee and assist with the work of the RFA.

Of course, that example is only for interest and comparison, as the governance policy actually used needs to be in accord with the other procedures in your facility. Assuring that harmonization is one of the essential function of the "procedures mentor" described below.

It is unusual (but certainly not unheard of - we have met some who are surprisingly good at it) to have a person who has all the other characteristics desirable for the RFA role to also be a skilled writer of procedure documents. Assume they will need support in completing these and in ensuring the procedures become standardized throughout the facility or system. For this, the RFA should be provided with a mentor with the requisite experience until they are capable of doing these alone.

We have attempted to keep this toolbox simple and achievable, and to avoid some of the more elegant but difficult ramifications of these processes. Nevertheless, we know that it all envisions an ideal. Getting to this level of highly developed processes and outcomes may require time and possibly investments to achieve, depending of course on where your program stands currently. We appreciate there is more than one pathway to the top, and you and your RFA are encouraged first to adapt these concepts to fit or improve your existing program. Remember, if you are currently getting through your accreditation surveys you are obviously already doing most things acceptably. The appointment of the RFA is your opportunity to climb up a few steps, not necessarily a mandate to mountaineer the summit.

Putting these procedures in place and assuring enforcement will require support. Particularly while the processes are new and still settling into use, consistent and visible support from the C Suite will be invaluable to your new RFA, and will ensure that you begin as you mean to go on, continuously improving the physical systems and operating practices that assure they help deliver positive clinical outcomes.

Welcome to the role

Now that you are the RFA, what are you expected to achieve?
Training and credentials.
Documents you need to have and know.
Who else will be involved?

We trust that since you are reading this, you have been assigned the role as your facility's Responsible Facility Authority. Congratulations, and welcome to what we know to be a challenging position, but a vitally important one which usually comes with real job satisfaction.

Let's begin by answering some questions. First, why does this role exist at all? Why did NFPA 99 specifically state that each facility must have a Responsible Facility Authority for medical gases?

The requirement comes out of the ongoing effort to ensure that medical gas systems are always operational and always safe for use. The NFPA 99 has progressively set out rules for how the systems should be constructed, what materials and techniques should be used to construct them, and ultimately how the people who build them are to be qualified. This effort has made a big difference over the years in reducing problems with new systems. It has also made it obvious that there are many problems that occur during operation of the systems. No standard can prevent this. Systems vary so much in their configuration, equipment types, condition, operating characteristics, etc., etc., that standards could never cover all the possibilities.

The only way to ensure that a system operates as it should is to ensure that the people using it know what to do and how to do it. But medical gas is only a small part of all that happens in a medical facility, and most people - even many who use them everyday - don't have all that much knowledge about them. That means they need someone knowledgeable to be available when the questions do come up, someone who can focus on making sure the systems are as they should be, and if something goes awry, is corrected promptly and without interruption of supply to the patients.

That person needs to know the systems intimately, know how they ***should*** work, know how they ***do*** work, know the standards, know the policies and procedures (and probably help write and update those), and make that expertise available to others who will need it. They are the facility's expert and primary resource on medical gas systems matters.

This is the role you have been assigned to fill.

In this booklet, we will work primarily with the RFA role as it is described in the NFPA 99 standard. Naturally, you will receive your full job description and mission from your manager. They will add or delete responsibilities to fit how your facility or healthcare system conceives you will be most able to support them. Your assigned responsibilities may then be somewhat greater or maybe something less than the description in this booklet.

Preparing yourself

Your facility has placed confidence in your ability to do the job, so you probably already have some or all of the qualifications. One required qualification is one of the credentials described in the ASSE 6000 ***"Professional Qualifications Standard for Medical Gas Systems Personnel"*** The credentials listed in NFPA 99 as suitable include the ASSE 6010 "Installer", ASSE 6020 "Inspector", ASSE 6030 "Verifier" and ASSE 6040 "Maintenance Personnel".

Although NFPA allows for any of these, it is clear from comparing the qualification and the role that the 6040 is the best fit, and thus if you need to get a qualification, we would recommend the 6040. Even if you have one of the others, we would recommend you consider getting the 6040 as well.

Be aware that none of these credentials are by themselves sufficient to succeed as an RFA. The credential classes are usually generic, so you will learn safety, terminology, and most important, the Code. You will not learn the specific systems in your facility, or the specific processes or procedures your facility follows, or even the typical operations involved in your job.

What other training might be useful? Any or all of the following can be useful to the RFA. If you have the skill, it should be practiced, and if not, learned:

- Reading and drafting engineering drawings,
- Diplomacy and negotiation,
- Writing and reading procedures, process mapping and flowcharting,
- Project management,
- Managing multiple priorities,
- "People skills",
- Quality management and regulatory compliance.

Your library and references

There are a number of reference documents and websites that you will find valuable from the start. You will also quickly identify others which will be useful to you.

Here is a starter's list of the most essential.

NFPA 99 Health Care Facilities Code
Available from NFPA.org/99

ASSE 6000 Professional Qualification Standard for Medical Gas Systems Personnel
Available from https://assewebstore.com/asse-iapmo-ansi-series-6000-2021/

NFPA 55 Compressed Gas and Cryogenic Fluids Code
Available from NFPA.org/99

mgpho.org
The Medical Gas Professional Healthcare Organizationis the verifiers professional organization. It is not directly connected to the role of the RFA, but is a very useful place for information and to ask questions on their Forum. You will undoubtedly have a lot of dealings with verifiers and this will be a useful resource.

ashe.org
The American Society for Healthcare Engineering is the nearest thing to a professional organization specific to you. The organization is all about advocacy and resources for healthcare facilities people. Their website is a great place to seek resources and insights.

jcaho.org
Joint Commission is probably your accreditation agency and you will be working with their survey teams. Even if your facility is accredited by another agency, the information available from JCAHO will be useful to prepare for and understand their expectations.

fgiguidelines.org
The Facilities Guidelines are very important if you undertake any construction or renovation work. They are mandatory in most states, and define critical things like how many outlets are required for each occupancy.

Who Else will be involved?
The RFA is no job for the reclusive. It requires interaction with many people throughout your organization on a continuous basis, and you will be more successful as you are able to build effective working relationships with the many stakeholders in the processes you'll operate.

You will of course start with your supervisor. Unless you are lucky enough to be in one of the very few organizations who has already pioneered the RFA concept, the idea of the RFA is new for them as well. They are learning with you what the role will involve and are seeking to appreciate what it can deliver for patient care.

The clinical staff is the primary user for the medical gases so their needs and wants must always top the list, second only to the patients for whom they speak. Generally clinicians are not too involved in the details, but they need to know (ideally well in advance) if the medical gases will be unavailable or compromised for any reason, and if so, they need to be provided with resources and tools so they can ensure patient care goes on uninterrupted.

The facilities team, maintenance mechanics, operators and contractors are all essential to actually getting your job done. If they are in the loop and buy into the goals, they will make the procedures work and produce the intended work product (along with that annoying but essential documentation that is always required).

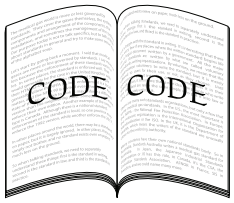
Suppliers will be central to many of the processes as agents, participants, and as resources for you. It will be well worth having working contacts with all the important suppliers so you can access their expertise and also assure their cordial cooperation.

Regulatory agencies and accreditation teams are one of the more difficult groups to deal with simply because they are not seen very often in a facility which is functioning well. People from the Health Department for instance may only ever get involved when new projects are contemplated or underway, and the accreditation team may never include the same individuals twice. Nevertheless, because they pass judgment on the effectiveness of what you do, and because they can be a resource for you, it is wise to know who they are and to build a relationship if possible.

Your Architects and Engineers will be essential resources for you, and you for them when your facility undertakes construction or renovation work.

Requirements > Policies > Procedures

How Requirements turn to Policy and to Procedure.



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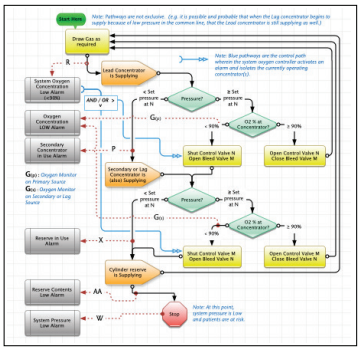

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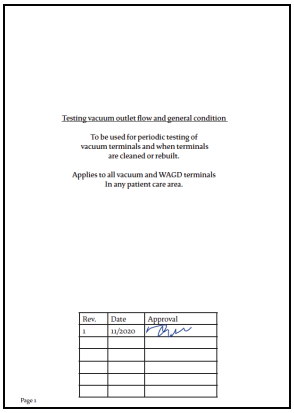


The requirements

The policies and processes

Standard operating Procedures (SOP)

The First Rule of Medical Gas is ***"Always Supply the Patients"***. Our overall goal can't be expressed any more simply.

The Second Rule is that ***"Medical Gases are Pharmaceuticals"*** - they are essential to the treatment of patients and the purity delivered to the patients is essential for the success of the treatment and for ethical and legal reasons.

Think: what could occur that would end with us breaking these rules? As we consider the possible scenarios we can prepare for them - or better yet figure out how to prevent them entirely. The simplest example is that we know if we don't maintain our equipment, it will eventually fail. First rule broken. Therefore, we want to do the required maintenance. That maintenance is something we can define, describe, plan, schedule and in short, manage.

In fact, any event that could interrupt supply can be defined, described, and planned for in the same way. Wrap all of that planning into a management and operation process for our medical gases, and it should be possible for us (or anyone else in future) to efficiently manage all of the scenarios we thought out .

In all this, a way to think of the NFPA 99 Code is as a summary of lessons learned through the experience of others. Simply following the requirements in the Code will take us a long way in identifying and reducing our risks.

The concept of what we are about is illustrated in Detail 17. We first have to first define our requirements. They will come from the Code and other legal mandates, from the manufacturer's maintenance requirements, from a common sense understanding of what is needed to make things work, and will be filtered by our own risk assessments. The facility's philosophies and strategic goals are also essential considerations. These define the goals we can use to measure success.

Then, to get to those goals from where we are, we need a map. That map is our management plan, and the policies and the processes of the facility. But like any map, it needs to be converted into a series of specific directions, telling what action to take at each turn and intersection. These specifics are our procedures or S.O.P.s.

As an example, maintaining the medical vacuum central supply system is a requirement of the NFPA code (NFPA 99 2021 5.1.14.7.7 (3)). To fulfill that requirement we first have to know what equipment we're working with. Then, we can use the original manufacturer's operating and maintenance instructions to describe the specific steps needed to maintain that equipment (checking the condition of the machine, changing or replacing the wearing elements and fluids, testing its' function, etc.)

So, in a very simplified form we can outline how we will build the medical gas management plan this way:

1. Determine what equipment we have,
2. Define the requirements for that equipment using the Code, manufacturer's requirements and recommendations, and risk assessments we do internally,

3. Plan for each requirement:
   - what needs to be done,
   - what operations are part of that process,
   - how often does each of those operations need to be done,
   - what preparation is needed to do each operation,
4. Detail the operations themselves in enough detail to enable anyone with the right qualifications to perform them,
5. Decide how to document that the work was done,
6. Test if the process is working and adjust it as needed.

Detail 17
General Process flow

1: Creating the map

NFPA 99 identifies six "work products" the RFA can expect to be involved with and therefore that will need effective policies, processes and procedures. Remember that some of this may already exist in your facility. (If you can start from something that already exists, it will greatly simplify your job).

1. Inventories. This is essentially a list of all the medical gas equipment. Naturally, particular attention needs to be paid to those items which are critical (e.g. those where a failure would put patients, staff or visitors at risk).

   See 99 5.1.14.4.2.1 and this guide Chapter 4.

2. Inspection plans and procedures. The items in the inventory will need to be periodically inspected, again with special emphasis on critical components or systems. This will require an inspection plan (a calendar, for instance) for the various inspections and details of how these inspections are to be done. Note that Inspection is NOT the same as maintenance and NOT the same as testing and verification (although inspection and maintenance operations are often be done at the same time for convenience.)

   See 99 5.1.14.4.2.2, 99 5.1.14.4.2.3, ASSE 6000 Annexes F through I, and this guide Chapter 5.

3. **Maintenance Schedules.** These are the typical PM (Preventative Maintenance) operations that will usually be drawn from the original manufacturer's operating and maintenance manuals.

   See 99 5.1.14.4.2.4, ASSE 6000 Annex D, and this guide Chapter 6.

Maintenance plans may also include standard operating procedures such as changing cylinders on a manifold. That is a decision you will need to make - will operating procedures be the subject of a separate set of procedures or part of the general maintenance process?

See 99 Chapter 11 and this guide Chapter 7.

4. **Emergency plans and procedures.** This is the "what to do if..." plan. It needs to consider at minimum all the equipment that is identified as critical in the inventory, and provide a plan for what to do if that equipment becomes unavailable for any reason that can be realistically anticipated.

   See 99 5.1.14.1.2.2 (2), ASSE 6000 Annex J, and this guide Chapter 8.

5. **The Permit to Work system.** This describes how the facility will control work that is done on the medical gas systems. Its intent is three fold: (1) to ensure communications between people who must know that work is to be done (particularly work that means shutting down the systems); (2) to ensure that only properly qualified and competent people do the work and (3) to ensure that the necessary testing is performed before the systems are returned to service.

   See 99 5.1.14.2 and this guide Chapter 8.

6. **Construction program.** This will be a set of processes to be followed when the facility undergoes construction or renovation work. Naturally, it will be very closely tied to the Emergency plan and to the Permit to Work system, so for many facilities it will simply be the part of those two which is used during construction.

   See 99 5.1.14.1.2.2 (3) and this guide Chapter 9.

Remember this cornerstone of quality management: Say what you do, Do what you say and Document all of it. The procedures are the "Say what you do" part. Everything you will undertake to do needs to be rooted in them. If your procedures are complete and sufficiently detailed, any audit or accreditation survey can quickly determine that you are "doing what you say" because they can see it in your documentation. And which will make your life much more comfortable.

Your facility may already have some of these procedures in place. It is usually much more effective to use what you have and adapt it over time (particularly if your time or competent resources are limited). Only if they don't exist or you need to make significant changes will it be necessary to write them from scratch. Annexes II and III in this guide are basic templates to consider.

There will need to be a "master"or "top level" procedure that organizes all of this. It would describe for instance how a new procedure is reviewed and approved, where they are kept, secured and accessed, who is responsible for them, probably an outline or sample procedure detailing what a procedure needs to contain, and how often they are reviewed. This master procedure is not only needed for medical gas processes, but will be used across the organization for all Standard Operating Procedures (SOP). Therefore, it probably already exists. If so, use it as your starting point in developing the procedures specific for medical gases.

Another procedure which is also not unique to your work but very essential is risk assessment. Quite a few situations will arise with medical gases where finding the answer will require you to "do a risk assessment" before making a decision or finalizing a policy. Risk Assessment is a formal process requiring specific input and outputs, with permanent documentation of the conclusions. Your facility may already have or will need to have such a procedure. Use that for your medical gas risk assessments as well. A risk assessment procedure is outlined in Annex II should you need it.

Writing good procedures

New procedures will have to be written all the time, such as when new equipment is installed, or old equipment is removed or modified. With a smoothly operating management program, rewriting will also need to be done as better methods are developed, experience is gained and risks are reconsidered. One of the first which will be needed in most facilities will be the Permit to Work process, since few facilities will already have this in place in the form NFPA 99 requires.

Procedures should include all the detail that is necessary to complete the task but no more. The longer and more complicated a process, the more likely steps will be missed or that the procedure will simply be ignored.

One should always assume that the operator is intelligent and capable of following the instructions, but take the point of view of an operator who has not performed this operation before. Illustrations are very useful and should be used profusely (they are easy to make using a cellphone camera and computer). Videos are very good as introductions, but are hard to remember or to search through when actually on site doing the work, so something simpler that can conveniently be referenced at the job site is probably better.

Remember that most adults don't read instructions and remember only a part of what they read anyway. Simpler and shorter is almost always better than long and complex, as long as the operations are described clearly and understandably.

A procedure needs to include at least these four parts:

1. General Information:
- What equipment does this procedure apply to;
- Where is that equipment located;
- When is this procedure to be used;
- When was the procedure written;
- Who wrote it.

2. Safety precautions and Pre-start preparation
- Hazards and cautions;
- PPE needed;
- Tools, Parts and supplies required;
- Permit to Work requirements for this process;
- Other preparation required.

3. Procedures (in order of performance)
- Goal of the process;
- The actual process (the how-to, step by step);
- Testing required (this may be in this process or in a separate step by step testing instruction).

4. Documentation
- Forms to complete or required data entry;
- Process for completing the forms and handing them in;
- Approvals or signoffs needed.

Any procedure will of course also need to include other information as required by your facility's master operating procedures (e.g. procedure number, approval signatures, effective date, review date, file number, etc.)

For a sample of a simple procedure that every facility will need, see this Guide, Annex IV.

2: Follow your procedures

The procedures will be written with the best intentions and following the information that is available at the time. If they are written clearly they should be easy to follow and produce the results expected. The documentation to back up the work should also flow out of the process.

If the work is done but the procedures are not used, then there is a disconnect that needs to be corrected. That does not mean that every maintenance tech has to carry around an instruction book - clearly most of them will know how to do most jobs from long experience and don't need the manual. But if the written procedure and the practice in the field are different, one or the other must change - ultimately the documentation and results need to match.

3: Learn from experience and capture the improvement

A new procedure is rarely perfect. Usually they will have a lot of rough edges and interpretation problems when they first get used. Also, over time, things change and a procedure may go out of sync with the actual practice or get in the way of improving how the job gets done. Converting practical experience into better procedures is an essential part of an effective program.

Procedures often suffer from ignoring or failing to implement input from the people actually doing the work, so they don't reflect actual practice and come to be seen as a stupid waste of time and paper. Regular review of processes is how experience gets worked into the procedures. A review may be a scheduled event, where a procedure has a review date, or it can be that the operator makes suggestions for improvement as they go. As long as the method is consistent and the changes are captured and used to drive improvements, the "how" can be flexible. The essence is to ensure that learnings from actual users of the processes are captured, implemented and that the learnings result in changes to the procedures accordingly.

Among the inputs to the review process will be comments from accreditation surveyors, particularly those around observed deficiencies. Aside from immediate corrective actions, the survey teams will want to see these findings corrected and procedures improved to prevent the problem recurring.

The inventory

The NFPA mandate.
What an Inventory should include.

NFPA 99 2021

5.1.14.4.2 Maintenance Programs

5.1.14.4.2.1 Inventories. Inventories of medical gas, vacuum, WAGD and medical support gas systems shall include at least all source systems, control valves, alarms, manufactured assemblies containing patient gases and outlets.

NFPA discusses a inventory of all medical gas equipment, which is clearly the foundation for the whole program. Development of inspection and maintenance programs for the equipment will build from the inventory.

An inventory is a pretty straightforward question - you need a list of all the medical gas equipment you have, including the important details about it. It can of course go much further, and to an extent it will go further as we build out the other required programs. The first step is collecting the information.

Before you start, you need to decide how you intend to manage the data you are about to gather. How will you keep it? In what format and where? Since the inventory will drive other essentials of your planning, how will the pieces fit together? There is also a finance and accounting dimension to the inventory which will interest the CFO (because of this, you may already have an inventory available through your accounting department and they probably also have a method for managing the data they use now).

A note of caution: most people think first of doing this with a spreadsheet. Unless you work in a very small facility, trying to do this on a spreadsheet is not really effective. If the management of data and working the computer takes more time than making improvements, your method is not working, so proper IT systems, programs and support will be essential. Commercial systems do exist that may help with this process, such as BeaconMedæs' ***myMedGas*** platform. If you can afford such an investment, it can greatly simplify the process.

Assuming you have worked out how you will manage your data, we can decide what elements you should include in the inventory. The following Table of Inventory Data Requirements details the equipment you might consider and the information which you will probably want to record about each item. Keep in mind that from the inventory we will be creating the Inspection and Maintenance plans, so we need to be sure we have enough detail in the inventory to do that. In particular, we need to have the manufacturer, model and possibly the serial number for each item so that we can access the Operation and Maintenance manuals or online assistance.

The handling of source systems are a significant question. Will you inventory them as a single "system" or will you inventory each component? Inventory at the component level makes the development of the maintenance and inspection plans somewhat more logical, but the same result will need to be achieved either way - inspection and maintenance operations will need to be planned at the level of detail called for by the operating manuals.

Inventorying terminals is always tricky. There are a lot of them, and if your facility uses asset labels, the labels can be unsightly. If you don't label them, and a room has several terminals of the same type, how do you tell one from the others? There is no standard method to do this, so what matters is that you establish a method that is clear and understood by everyone, so that one method can be used consistently.

Pages 24-35 are a starting point for the inventory. Each type of equipment you are likely to encounter is summarized along with the minimal details you will need to work with it in our later steps (note that no facility is required to have any specific equipment listed here. Simply use the sections relevant for systems you have).

Table of Recommended Inventory Data Requirements	
Note that this listing may not include every item your facility or your process will need. You should add to this anything which you believe will be useful in the development of your inspection and maintenance program.	
Equipment Type	Notes
Terminals	
Location	this can be tricky. It is necessary to create a uniform shorthand that can be used to identify each terminal unit relative to others consistently by any user (see example below)
Service (gas)	
Manufacturer	
Keying system	
Series or Model	this is essential for identification of repair parts
Date of installation	
Asset code(s)	if used by your facility

A sample terminal unit location protocol (note this is only needed in rooms containing many outlets where one must be distinguished from all others):

To determine and record location of outlets:

1. Standing as close to the middle of the room as possible, designate the entrance door as the starting point (if there is more than one door, note which one is being used)

2. Letter the walls as you spin clockwise around the room (A,B,C,D,E, etc.) A is always the wall with the door and ALL walls are lettered (even if they have no outlets).

3. Where outlets are on the side of fixed columns, the column is treated as a wall and given a letter designation like all other walls clockwise from the face closest to the door. Where there are multiple columns, their faces are lettered in order from the nearest to the door, always proceeding clockwise.

7. Movable booms are lettered starting from the face with the largest number of outlets, then clockwise around the head. Where two faces have the same number of outlets, the number of specific gases are considered in the order: O, N2O, MedAir, Vac, WAGD, IAir/N2, CO2) with the face containing the largest number of outlets of the highest priority gas becoming the starting face and lettering clockwise.

8. Read the outlets left to right as you face them.

9. If outlets are stacked at multiple levels, read top tier left to right, then next tier left to right, etc.

10. Ceiling outlets and outlets on the bottom of fixed columns are read as if laying on the floor with your head pointed to the "A" wall in that room, top left to top right to bottom left to bottom right. Do not consider the orientation of the outlet, only its position in that sequence.

Specialty patient environment assemblies	this would be used for any assembly containing medical gases which uses hoses internally (e.g. booms, pendants, ceiling columns, headwalls, trunking systems, service units, etc.). It would not be needed for assemblies which contain medical gases but are hard piped, as only the individual elements in those (e.g. terminals) will need to be considered.
Type	
Location	
Services (gases)	each terminal also needs to be listed separately as a terminal unit (see Terminals)
Manufacturer	
Series (whole unit)	
Date of installation (whole unit)	
Asset code(s)	if used by your facility
Internal Hoses (hoses inside these assemblies)	
End fittings	this is the system used to connect the internal hoses to the pipeline at one end and to the terminal units for the user at the other.
Date of installation	the hoses must be dated for their date of installation (see NFPA 99 5.1.6.9.(4)) This will be used to determine the replacement schedule.
Asset code(s)	if used by your facility

Zone Valves

complete one for each zone valve assembly

	Location	
	Services (gases)	
	Manufacturer	
	Valve Sizes	
	Date of installation	
	Asset code(s)	if used by your facility

Other Valves (inline, future, service, riser, main line and source valves)

complete one for each valve

	Location	
	Service (gas)	
	Manufacturer	
	Valve Size	
	Date of installation	
	Tag number	if numeric tagging and/or keying are used to label valves in your facility
	Key number	
	Asset code(s)	if used by your facility

Alarms

complete one for each alarm panel

	Location	
	Included signals	
	Manufacturer	
	Date of installation	
	Model number	
	Serial number	
	Asset code(s)	if used by your facility

Alarm Sensors

ideally, complete one for each sensor or switch. This can get overwhelming, so it may be easier to group all the sensors for a given alarm together if they are located together.

	Location	
	Service (gases)	
	Panel actuated	
	Manufacturer	
	Model number/ serial number	This is not always possible - some sensors are not marked
	Connection	This is important to knowing how to service the sensor, particularly if the sensor is not on a demand check.
	Date of installation	
	Asset code(s)	if used by your facility

Manifolds		
complete one for each manifold panel		
	Location	
	Service (gas)	
	Manufacturer	
	Model number/ serial number	
	Cylinders/ Containers	number of connection points
	CGA fitting	needed only for gas mixtures
	Date of installation	
	Asset code(s)	if used by your facility
Cylinder reserves		
complete one for each separate header (not those which are part of a manifold control)		
	Location	
	Service (gas)	
	Manufacturer	
	Model number/ serial number	
	Cylinders/ Containers	number of connection points
	CGA fitting	needed only for gas mixtures
	Date of installation	
	Asset code(s)	if used by your facility

Cryogenic fluid central supply systems		Note that these are often not owned by the facility. All these details may be available from the gas supplier.
	Location	
	Service (gas)	
	Manufacturer	may prefer to list supplier if you do not own the container
	Primary Container	
	Model number/ serial number	
	Size	
	Date of installation	
	Asset code(s)	only if the container is owned by your facility
	Secondary or Reserve Container	
	Model number/ serial number	
	Size	
	Date of installation	
	Asset code(s)	only if the container is owned by your facility
	Reserve Container	If used. Otherwise, if a cylinder reserve is provided, use "Cylinder Reserves".
	Model number/ serial number	
	Size	
	Date of installation	
	Asset code(s)	only if the container is owned by your facility

Medical air central supply systems		
	Location	
	System Manufacturer	
	System Model number/ serial number	
	Configuration	duplex, triplex, etc.
	Date of installation	
	Asset code(s)	if used by your facility(1)
	Compressor	complete one for each compressor in the central supply system
	Location / designation	
	Manufacturer	
	Model number/ serial number	
	Motor Hp.	
	Motor Model number/ serial number	
	Dryer	complete one for each dryer in the central supply system
	Location / designation	
	Manufacturer	
	Model number/ serial number	
	Filter	complete one for each filter in the central supply system
	Location / designation	
	Manufacturer	
	Model number/ serial number	
	Pressure Regulator	complete one for each regulator in the central supply system
	Location / designation	
	Manufacturer	
	Model number/ serial number	
	Dew point monitor	Note that in some systems, these monitors are separate from the system and therefore might have separate inventory codes
	Manufacturer	
	Model number/ serial number	
	CO monitor	
	Manufacturer	
	Model number/ serial number	

Concentrator central supply systems		
	Location	
	System Manufacturer	
	System Model number/ serial number	
	Configuration	simplex concentrator with cylinders, duplex concentrator with cylinders, etc.
	Date of installation	
	Asset code(s)	if used by your facility (1)
	Supply Source (Concentrator Train)	complete for each Supply Source in the central supply system
	Location / designation	
	Manufacturer	
	Model number/ serial number	
	Compressor Manufacturer	
	Compressor Model number/ serial number	
	Compressor Motor Hp.	
	Compressor Motor Model number/ serial number	
	Concentrator Manufacturer	
	Concentrator Model number/ serial number	
	Air Dryer Manufacturer	

	Air Dryer Model number/ serial number	
	Filter Location / designation	complete for each filter in the central supply system
	Filter Manufacturer	
	Filter Model number/ serial number	
	Supply Source isolation valve manufacturer	
	Supply Source isolation valve Model number/ serial number	
	Oxygen Monitor manufacturer	this is for the Supply Source monitor
	Oxygen Monitor Model number/ serial number	
Oxygen Monitor		this is for the Central Supply System monitor
	Oxygen Monitor manufacturer	
	Oxygen Monitor Model number/ serial number	
Pressure Regulator		complete for each regulator in the central supply system
	Location / designation	
	Manufacturer	
	Model number/ serial number	
note: for the cylinder reserve, use table for “Cylinder Reserves” or “Manifolds”		

Medical vacuum central supply systems		
	Location	
	System Manufacturer	
	System Model number/ serial number	
	Configuration	duplex, triplex, etc.
	Date of installation	
	Asset code(s)	if used by your facility (1)
	Pump	complete for each pump in the central supply system
	Location / designation	
	Manufacturer	
	Model number/ serial number	
	Motor Hp.	
	Motor Model number/ serial number	
	Vacuum Filter	complete for each line filter in the central supply system
	Location / designation	
	Manufacturer	
	Model number/ serial number	

Instrument air central supply systems (NFPA 99 IAir)	
Location	
System Manufacturer	
System Model number/ serial number	
Configuration	simplex, duplex, with cylinder reserve, etc.
Date of installation	
Asset code(s)	if used by your facility (1)
Compressor	complete for each compressor in the central supply system
Location / designation	
Manufacturer	
Model number/ serial number	
Motor Hp.	
Motor Model number/ serial number	
Dryer	complete for each dryer in the central supply system
Location / designation	
Manufacturer	
Model number/ serial number	
Filter	complete for each filter in the central supply system
Location / designation	
Manufacturer	
Model number/ serial number	
Charcoal Canister	complete for each canister in the central supply system
Location / designation	
Manufacturer	
Model number/ serial number	
Pressure Regulator	complete for each regulator in the central supply system
Location / designation	
Manufacturer	
Model number/ serial number	
Dew point monitor	Note that in some systems, these monitors are separate from the system and therefore might have separate inventory codes
Manufacturer	
Model number/ serial number	

Instrument air source (ISA s-7.0.01 IAir)	
Location	
System Manufacturer	
System Model number/ serial number	
Configuration	simplex, duplex etc.
Date of installation	
Asset code(s)	if used by your facility (1)
Compressor	complete for each compressor
Location / designation	
Manufacturer	
Model number/ serial number	
Motor Hp.	
Motor Model number/ serial number	
Dryer	complete for any dryer provided
Location / designation	
Manufacturer	
Model number/ serial number	
Filter	complete for each filter provided
Location / designation	
Manufacturer	
Model number/ serial number	
Charcoal Canister	complete for any canister provided
Location / designation	
Manufacturer	
Model number/ serial number	
Pressure Regulator	complete for any regulator provided
Location / designation	
Manufacturer	
Model number/ serial number	

WAGD central supply systems		
Note: a venturi WAGD inlet would be classified with Terminals		
	Location	
	System Manufacturer	
	System Model number / serial number	
	Configuration	duplex, triplex, etc.
	Date of installation	
	Asset code(s)	if used by your facility (1)
	Pump	complete for each producer in the central supply system
	Location / designation	
	Manufacturer	
	Model number/ serial number	
	Motor Hp.	
	Motor Model number/ serial number	

(1) *Facilities typically code a source system as a single asset. However, it is also possible to code components separately. If this is done, a place to record the separate component's asset code(s) will need to be added.*

Inspection plans and execution

The NFPA mandate.
What to inspect and when.
Inspection procedures.
Record keeping

NFPA 99 2021

5.1.14.4.2.2 Inspection Schedules. Scheduled inspections for equipment and procedures shall be established through the risk assessment of the facility and developed in consideration of the original equipment manufacturer recommendations and other recommendations as required by the authority having jurisdiction.

5.1.14.4.2.3 The facility shall be permitted to use any inspection procedure(s) or testing methods established through its own risk assessment.

5.1.14.4.3.1 Manufactured Assemblies Employing Flexible Connection(s) Between the User Terminal and the Piping System.

(A) Nonstationary booms and articulating assemblies, other than headwalls utilizing flexible connectors, shall be tested for leaks, per manufacturer's recommendations, every 18 months or at a duration as determined by risk assessment.

(B) The system pressure to nonstationary booms and articulating arms shall be maintained at operating pressure until each joint has been examined for leakage by effective means of leak detection that is safe for use with oxygen.

(C) Safe working condition of the flexible assemblies shall be confirmed.

(D) DISS connectors internal to the boom and assemblies shall be checked for leakage.

(E) Leaks, if any, shall be repaired (if permitted), or the components replaced (if required), and the equipment retested prior to placing the equipment back into service.

(F) Additional testing of nonstationary booms or articulating arms shall be performed at intervals defined by documented performance data.

5.1.14.7.2 The supplier of the cryogenic fluid central supply system shall upon request provide documentation of vaporizer sizing criteria to the facility.

5.1.14.7.3 An annual review of the cryogenic fluid central supply system capacity shall be conducted to ensure the source system has sufficient capacity.

5.1.14.7.4 Central Supply systems for nonflammable medical gases shall conform to the following:

(1) They shall be inspected annually.

(3) A record of the annual inspection shall be available for review by the authority having jurisdiction.

5.1.14.7.5 A periodic testing procedure for nonflammable medical gas and vacuum and related alarm systems shall be implemented.

5.1.14.7.8 Audible and visual alarm indicators shall meet the following requirements:

(1) they shall be periodically tested to determine they are functioning properly.

(2) Records of the tests shall be maintained until the next test is performed.

5.1.14.7.9 Medical-Surgical vacuum station inlet terminal performance, as required in 5.1.12.4.10.4 shall be tested as follows:

(1) on a regular preventative maintenance schedule as determined by the facility maintenance staff

5.1.14.7.10 Where oxygen central supply systems using concentrators are used and one or more of the three sources is a cylinder header, the facility shall establish procedures to ensure the facility is always provided with one average day's supply of oxygen meeting the supply system product purity specification in reserve, as follows:

(1) the facility shall establish a minimum cylinder pressure that will permit one average day's supply. That value will be included as part of the standard operating procedure for the oxygen supply system.

(2) The cylinders will be inspected daily and any loss of pressure noted.

(3) When the cylinders are found to have lost pressure due to use or leakage and thus are below the pre-established pressure, the cylinders shall be exchanged.

5.1.14.7.11 Access to valves and alarms shall be made part of the standard operating procedures for the facility and shall include the following:

(1) No items are to be placed in front of or affixed to any alarm panel that would restrict the view or diminish the sound of the alarm.

Medical gas is life support. So any event or a failure which might mean we break the First Rule - to always supply the patient, has to be managed. If we know a problem could occur, we can take action to prevent it. So that we do know, the Code expects us to perform inspections.

In the Code, an interval is not generally part of the mandate (although there is an exception for booms and assemblies with internal hoses) but is left largely for the facility to decide. The greater the risk, the more frequent the inspection.

One of the first tasks for the planning process is to decide these priorities. This is tough, since all medical gas equipment is by it's nature more or less critical.

A simple example is a manifold. By design, it has inherent redundancy so when one header is empty, the other takes over. The patient remains supplied. So a changeover alarm is less critical than a low pressure alarm would be on that same system. Low pressure means supply has failed, and therefore that requires immediate attention - drop everything, run and figure out what's wrong kind of attention.

A changeover alarm is a normal part of system operation. In a well sized system, one can expect that alarm to go off about once a week. Low pressure on the other hand is an alarm that no one should ever see. There is no need for "inspection" of a changeover signal - in a sense it is 'self inspecting'. But the low pressure alarm will need exercising if we are to be sure it functions when we need it.

Another example would be a room with one oxygen outlet. Under some circumstances, that outlet will be critical. However, if the room had two outlets, that same circumstance would not be so critical simply becasue there is redundancy.

So as we set out the Inspections plan, these are the kind of considerations we need to factor in, along with the manufacturer's recommendations, our utilization (particularly on rotating equipment) and other specific risks that we are out to prevent.

The classic approach to setting these priorities is the "Failure Mode Effects Analysis" (FMEA). Such an analysis is not very difficult to do once the basic principles are understood. Annex II describes how to go about performing this analysis.

The list of inspections developed from your FMEA analysis is the foundation of the Inspections plan. To that basic list you will need to add:

1. Equipment needed. Tools and instruments required to perform each inspection;
2. Timing. How often will each inspection need to be performed;
3. Work instructions on how to perform each inspection;
4. Documentation - how and where each inspection needs to be documented and what results you need recorded.

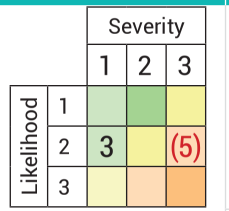
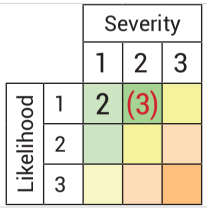
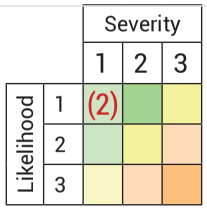
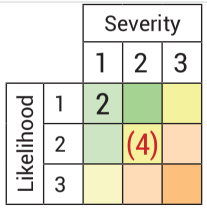
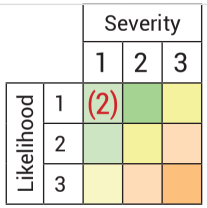
It may be useful to include documentation as a column in your FMEA. In that way you can quickly know where to look during an audit to validate the work was done.

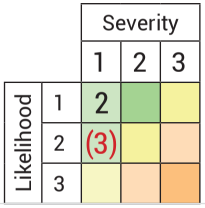
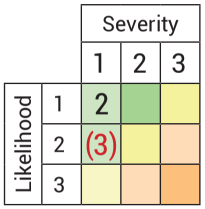
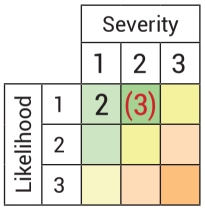
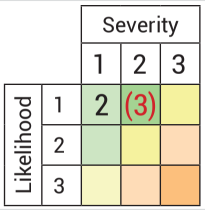
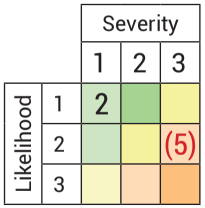
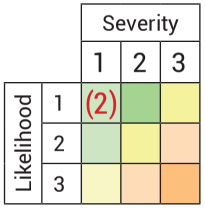
All of this will seem overwhelming if you have not done this before or been trained in the process. Fortunately, we have the Code which is essentially the accumulated experience of others in all this. It can be a very useful starting point for these analysis. The trick to making it meaningful is to consider the why behind the requirement rather than the code language itself.

This is the basis of the sample FMEA in Table 44 which follows NFPA 99, and is referenced to the Code. To this outline, you will need to add your own considerations on potential failure modes, causes, and preventive actions, and consider if the generic actions in the template are correct and sufficient for your facility.

One final note. If you are using any instruments to perform inspections or tests (e.g. flowmeters, dew point monitors, gas analysis equipment), remember that the instruments themselves must be periodically checked and calibrated. These instruments need to be added to the Inspections and maintenance plans along with the other med gas equipment.

Table 44 Example of a Medical Gas Failure Mode and Effect Analysis

The failure		The consequence	How could this happen?	Risk matrix	Prevention plan	Inspection plan	Notes
#	Med Air quality out of specification	Air not to USP specification going to patients	Intake contamination		Monitor intake location; CO Monitor;	• Check intake location annually and if CO alarm occurs. • Do USP quality test annually	
Ref: 99 5.1.3.6.1; 5.1.3.6.3.11			Compressor failure		Compressor P.M.		
#	Med Air misapplication	More air use than is expected or for which the system was designed	Staff misuse		Monitor use	Observation in daily rounds	could be serious but only if continued for a long time or very severe.
Ref: 99 5.1.3.6.2							
#	Med Air Location: Compressor Room not constructed to standard	Compliance	Construction changes		Check all construction documents for compliance	Verification with new construction	verifier should identify this with new work.
Ref: 99 5.1.3.6.3.1							
#	Med Air Location: Compressor Room ventilation	Overheating of compressor, Possible problems with dryers and controls	Ventilation failure		Keep ventilation system in good operating condition	• In daily rounds - note room temperature and record temperature at controls • Listen for normal fan sounds • Observe temperature alert on controls	
Ref: 99 5.1.3.6.3.1							
#	Med Air Components	Compliance	• New system install • System replacement		Check all construction documents for compliance	• All work by qualified vendors and installers • Verification with new construction	basic requirement of the verifier in new work.
Ref: 99 5.1.3.6.3.2 (1)							

#	Med Air Components: Check valve failure	• Possible damage to compressor • Inability to service the compressor without shutdown	Valve failure to close, bad seals		Compressor P.M.	Check as part of P.M.	
Ref: 99 5.1.6.3.2 (2)							
#	Med Air Components: Compressor inlet filter failure	• Possible damage to compressor	Filter clogged or overloaded (not changed)		Change as required by mfr. instructions or if change indicator is activated.	Check as part of P.M.	
Ref: 99 5.1.6.3.2 (4)							
#	Med Air Components: Relief valve failure	• Possible damage to compressor valves • Possible damage to regulators	• valve plugged, • valve stuck from age		Replace as required by Mfr.	Check as part of P.M.	
Ref: 99 5.1.6.3.2 (5)							
#	Med Air Components: wrong components	• Possible damage to compressor, • Possible contamination of the air,	Dirty or oily components		Use original mfr. components	Check as part of P.M.	
Ref: 99 5.1.6.3.2 (7)							
#	Med Air Drying	• Water in air	• Dryer failure, • Incorrect system operation (pressure and temperatures)		• Ambient temp. See #4, • Aftercooler P.M., • Dryer P.M. • Dew point monitoring	• Check as part of P.M. , • Include in Annual checks • Dew point monitor calibration	
Ref: 99 5.1.6.3.3; 5.1.3.6.3.7; 5.1.3.6.3.13							
#	Med Air Components: Compressor seal failure	• Introduction of oil to the systems from seal failure • Dryer failure	Compressor seal failure (internal bearings)		Replace bearings or entire compressor as recommended by mfr. instructions	Track hours of operation vs. mfr. instructions	
Ref: 99 5.1.6.3.4 (A) (1)							

Maintenance plans & execution

The NFPA mandate.
Creating a maintenance plan.
Record keeping.

NFPA 99 2021

5.1.14.4.1 Health care facilities with installed medical gas, vacuum, WAGD, or medical support gas systems or combinations thereof shall develop and document periodic maintenance programs for these systems and their subcomponents as appropriate to the equipment installed.

5.1.14.4.2.4 Scheduled maintenance for equipment and procedures shall be established through the risk assessment of the facility and developed with consideration of the original equipment manufacturer recommendations and other recommendations as required by the authority having jurisdiction.

5.1.14.4.2.5 (A) Persons maintaining these systems shall be qualified to perform these operations.

5.1.14.7.4 Central Supply systems for nonflammable medical gases shall conform to the following:

(2) They shall be maintained by a qualified representative of the equipment owner.

5.1.14.7.7 Procedures as specified shall be established for the following:

(1) Maintenance programs for the medical air compressor supply system in accordance with manufacturer's recommendations.

(2) Facility testing and calibration procedure that ensures carbon monoxide monitors are calibrated at least annually or more often if recommended by the manufacturer.

(3) Maintenance programs for both the medical surgical vacuum piping system and the secondary equipment attached to the medical surgical vacuum station inlets to ensure the continued good performance of the entire medical surgical vacuum system.

(4) Maintenance programs for the WAGD system to ensure performance.

(5) Facility testing and calibration procedure that ensures that oxygen concentration monitors as calibrated at least every three months or more often if recommended by the manufacturer.

(6) Where oxygen sources include concentrator units, maintenance programs for the oxygen concentrator units and all essential subcomponents.

The chances are that your facility already has a maintenance plan that includes at least the major pieces of medical gas equipment. That plan is probably complete with schedules and all the other required items discussed here. Clearly, there is no value in redoing any plan that is already in operation, passing accreditation and otherwise effective.

If you are lucky to already have one, the maintenance plan will only need to be reviewed to ensure it contains all the elements you identify in your FMEA/Risk Analysis (see Annex II), and that the documentation on the performance of the medical gas aspects of the plan is accessible when it comes time to demonstrate performance (e.g. during your accreditation survey).

In the case where a plan may not exist, has been shown to be inadequate to the point it requires an overhaul, or the most likely case, where equipment is changed or added and no planning has yet been done, a plan will need to be created.

There are four aspects to a maintenance plan:

1. Purpose: What are you going to do (and why)
2. Schedule: When are you going to do it
3. Operations: What are the specifics of what will be done - tools, parts, operations, cleanup and testing.
4. Documentation: How and where will you record what has been done.

Setting the Purpose

The purpose will of course seem self-evident. We want to keep the equipment running so we don't violate our two rules of medical gas. While this is exactly right, we need to be a bit more precise. Being too broad opens up the problem of "everything needs maintenance" and we don't have infinite resource and could not handle it.

There are two main ways purpose can be more exactly described, and these are of course tightly interrelated: first, our FMEA analysis, which identifies the equipment and the risks we plan to control using maintenance as the primary tool, and second, the original manuals for the equipment, which lay out the mandatory actions required by the manufacturer if we want to maintain our warranty, keep the equipment in prime condition, or (if those aren't motivating

enough), just to control our liability. The first of these is about risk, the second, also about costs.

The assessment then will then be in two steps as well. One will draw from the FMEA worksheet all the items which have preventative maintenance as part of the prevention plan. This list should then be reviewed to ensure all the systems are included. Any systems or equipment which is not included (for instance, you may have an air system for central sterile decontamination - which is not a medical gas, but still important) will still need to be considered for maintenance, which then is the next step.

Collecting the manuals for all of the equipment will take some effort, especially with legacy equipment. Any reputable manufacturer will be able to help you with this, but of course the brand names have changed as has the brand ownership over the years, and really old equipment may simply no longer be supported. If the original manuals cannot be obtained, then you will need to use your best judgment as to what maintenance operations make sense.

From these, you can develop a list of all the required maintenance operations. Three things candssss be constructed during this process:

1. A calendar or schedule
2. A tools and parts list
3. A list of skills required, and from that a training list

Detail 50 illustrates the idea.

While you are working on this list, it also makes sense to cross link the manuals to this sheet (as shown). Generally speaking, using the manuals keeps you from having to write your own procedures (see Chapter 7). But it will be essential that the manual be accessible and the relevant instruction be easy to find when the work needs to be done. That information where to look to find the relevant part of the manuals should be included in the Tools section of the sheet.

Of course you also need to consider the problem of where and how the manual is going to be kept. Paper manuals don't fare well when mechanics must use them at the work site, so some form of electronic storage and retrieval system is highly recommended. The method used to retrieve the manuals can then be part of the basic training given to every maintenance technician.

As with everything, record keeping is essential. What is recorded is done, so how will you record the work, where will you store the records and how will you make them easy to access at accreditation time?

There are two aspects to this - the work itself, which includes recording that the operation(s) were performed, along with any comments that might be important to the next person doing the work or for planning purposes. The other aspect is the financial side, which will be the parts that were used and the time needed to get the job done. Detail 52 is a format that illustrates the important points.

Of course, all this is only part of the overall maintenance management program for your facility, so you will typically only need to ensure that the medical gas program is complete and included in the larger plan.

Detail 50: Sample Maintenance operations list

FMEA reference	Operation	Frequency	Tools	Required parts	Skills needed	Training requirement
	Vac Pump - change oil	every 2000 running hours	open end wrench 12 mm Manual 6170-0000-002 pp.16-18	5 qts synthetic oil, 8197-1390-000 (if changing the whole set of 3 use 15 qts.)	Basic mechanical	None
			oil filter wrench, automotive style; Manual 6170-0000-002 pp.18-19	1 ea. Spin on oil filter, 8197-1390-013 (if changing the whole set of 3 use 3 ea.)	Basic mechanical	None
	Vac Pump-change demisters	every 3 oil changes or 6,000 running hours	10mm hex key socket Torque wrench; Manual 6170-0000-002 pp.20-23	4 ea. demister filters, 8197-1380-113 (if changing the whole set of 3 use 12 ea.)	Basic mechanical	Experienced operator should observe a new operator first time.
				1 ea. end plate gasket, 8197-1380-120 (if changing the whole set of 3 use 3 ea.)		

Detail 52: Example of a maintenance record

Machine Details	Technician
Medical Vacuum Plant Location: 4th Floor Mezzanine, Rm# 4-232 Key 34622-6	

Operation	Completed (Date/time)	Comments	Parts used
Vacuum pump #1 1000 operating hour oil change	___/___/_____ Start: ___:___ Finish: ___:___	Current Hours _____	❒ Pump oil, 4 qt. ❒ oil filter, 1 ea.
Vacuum pump #2 1000 operating hour oil change	___/___/_____ Start: ___:___ Finish: ___:___	Current Hours _____	❒ Pump oil, 4 qt. ❒ oil filter, 1 ea.
Vacuum pump #3 1000 operating hour oil change	___/___/_____ Start: ___:___ Finish: ___:___	Current Hours _____	❒ Pump oil, 4 qt. ❒ oil filter, 1 ea.
System Filter Change	___/___/_____ Start: ___:___ Finish: ___:___		❒ filter element, 5 ea. ❒ filter change PPE and disposal kit, 1 ea.

Emergency plans

The NFPA mandate.
Creating an emergency plan.
Testing the plan.

NFPA 99 2021

5.1.14.1.2.2 The Responsible Facility Authority shall be responsible for the following:

(3) Ensuring that the health care facility's emergency plan specifically addresses unusual or exceptional requirements necessary for patient and staff safety arising from elements of design or construction of the building.

12.5.3.3.6.5 Essential Utilities and Systems. The facility shall plan for continuity of operations during the loss or interruption of the following utilities and systems during an emergency, as applicable:

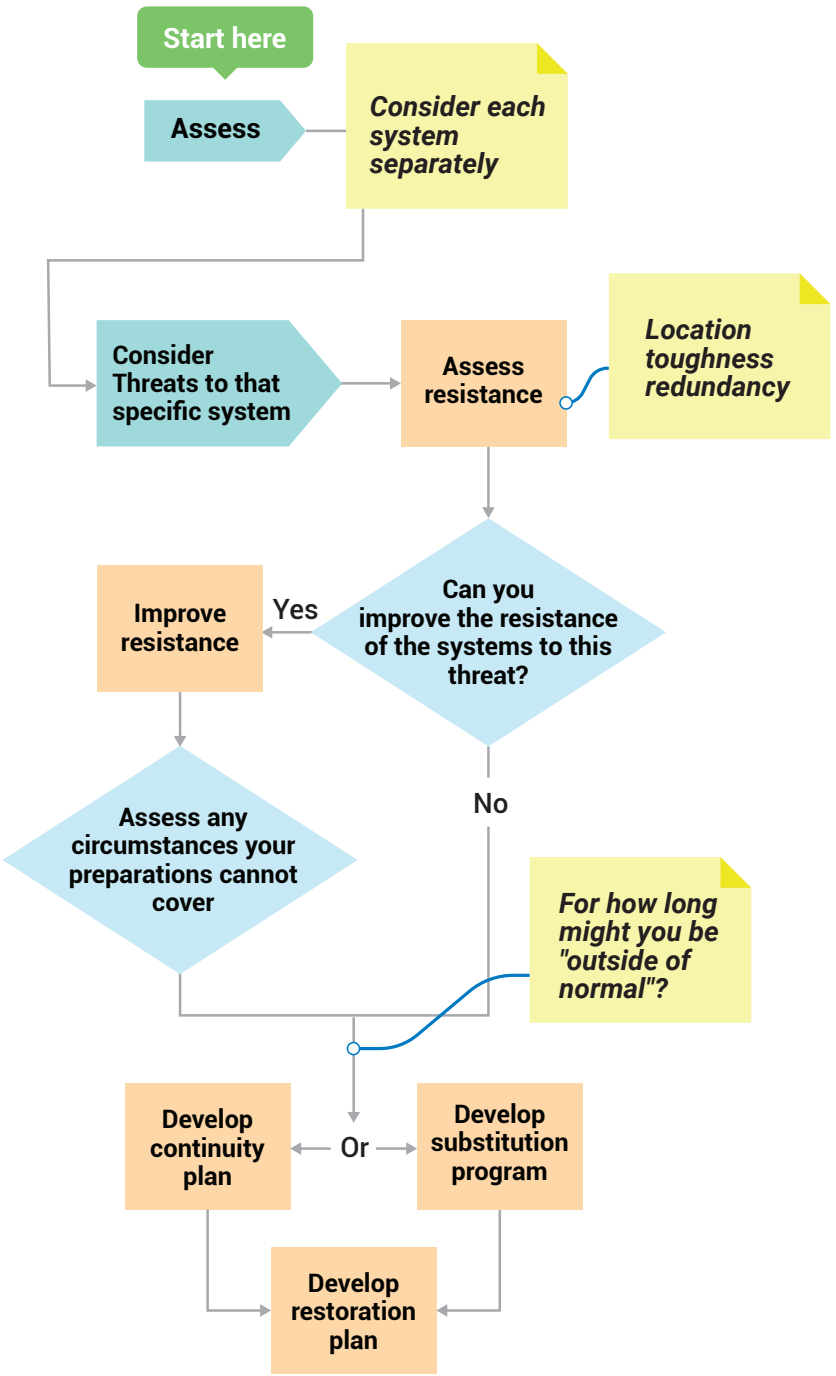
...

(9) Medical gas and vacuum

The RFA will typically be a member of or a contributor to the "Emergency Management Committee" required in NFPA 99 2021 12.2.3. They will be involved with the development of the medical gas portions of the required emergency program, specifically in the Hazard Vulnerability Analysis (HVA) (12.5.3.1), Mitigation (12.5.3.2) and Preparedness (12.5.3.3)

What do these responsibilities involve? The concept of course is to ensure that the facility has considered, planned for and put in place the procedures and equipment needed to deal with any emergency which can be reasonably anticipated. The RFA will of course be concerned with general emergencies which concern the facility overall (fires, flooding, seismic events, etc.) These will be defined by your facility's Emergency Management Committee as part of their overall Hazard Vulnerability Analysis (HVA). The RFA will add to that list problems which are relevant mainly or only to the medical gas systems.

Of course, many or most of the events that would be seen as emergencies may be covered in the FMEA analysis and managed through the FMEA, inspection and maintenance plans. What will qualify as an "emergency" in this context then will be the more extraordinary or rare event which cannot be prevented through ordinary actions within our



Detail 55
Emergency Planning flow

control. That does not mean that the tangible result may not be very like any more ordinary failure. After all if you lose your supply it doesn't really matter if it's because of poor maintenance or a catastrophic event, because the patient is equally at risk. However, in an emergency as considered here, there is likely to be more use of alternative and temporary expedients during the event and there may be unusual resources and procedures required to restore normal operation.

As an illustration, we could lose our medical air supply by any of a long list of events. Loss of supply by the failure of the controls would be considered in the FMEA and dealt with through ordinary planning, inspection and preventative maintenance programs as described in previous chapters. In contrast, loss of supply caused by collapse of the mechanical room in a seismic event would be a subject for emergency planning. It would involve preparations that one would hope never to need, such as connections for temporary sources, interconnections between buildings, prepositioned cylinder headers and a variety of other possible expedients.

NFPA clearly understands and accepts that in an emergency actions may need to be taken that would never be accepted under ordinary conditions. Those extraordinary actions may be equally difficult to unwind when the emergency is over and the facility sets out to recover. A good emergency plan also considers the process to restore normal supply.

There is a considerable side benefit to this work. By ensuring resistance to failure in a disaster, we also ensure that the systems can resist ordinary problems as well. Thus we can avert many of the small crisis that can be an irritating part of operating these systems.

What are the issues to consider? There are two primary branches. One is how we prepare should our facility be in the area where the disaster occurs. Earthquake, tornado, flood and hurricane are all events that could directly touch a facility in certain areas. Extreme snowfall and ice storms might be a consideration for some facilities.

The other branch involves events that the facility might not experience directly but is in line to feel the effects. A profound example is the experience of hospitals in Manhattan who experienced 9-11, or the hospitals in Tokyo who felt the knock on effects after the Tōhoku tsunami. Such events would of course include all of the above, but might also include civil unrest and industrial accidents. These events will not generally directly effect the medical gas systems, but may interrupt supplies for indeterminate periods.

With medical gases at the most basic level there are three specific considerations:

(1) Design for resistance.

(2) Continuity during the worst times.

(3) Recovery and Restoration to normal.

The gases can be ranked in importance. The "big two" are usually oxygen and vacuum. In facilities with neonatal patients, medical air will be close behind. Some facilities will find it difficult to cope without nitrogen or instrument air, but they will generally be those facilities where these gases are needed for trauma related surgeries. Elective surgeries requiring these gases would be assumed to be deferred during a serious emergency.

Clearly, design up front is the most effective part of preparing. Every action executed during the design phase saves unimaginable trouble during the tough times. Design for emergency preparedness should revolve around the concepts of fundamental resistance and of supply in depth.

Resistance starts with paying attention to the standard. After all, NFPA is fundamentally all about design of systems that can operate through any single fault failure. Simply by ensuring the systems meet the standard you have gone far toward preparing for at least the basic emergencies.

Some preparations are self evident. Providing seismic flex connections at key points in the medical gas lines is a must irrespective of the assumed severity of seismic events. Using horizontal rather than vertical oxygen bulk tanks, and installing barricade type cylinder restraints rather than simple chains are all considerations which may increase the facility's resistance in seismic areas.

The aspect of resistance that is important in medical gases is the vulnerability of the sources. The "big white tank" in the parking lot is vulnerable to any of several of the hazards mentioned, and its security clearly is an important consideration. Many facilities keep other gases in the same enclosure and of course these then are subject to the similar risks.

Consideration should also be given to the possible effects of airborne contamination. For instance, in an industrial accident or a fire near the facility, atmospheric conditions may make it undesirable to use the normal air intake, and alternative methods of supplying or purifying medical air may need to be provided.

Internal isolation may be a factor as well. For instance, a facility may have a perfectly operational source, but find it out of reach. Examples would include seismic events that

could rupture the interconnecting lines, or flooding which would isolate a source located in a separate building. Obviously, design for resistance will require that these possibilities be considered and alternative locations be considered. A good example of this comes from the many facilities who now put their major mechanical systems (including medical gases) on the second floor or above instead of the basement. This increases resistance to flooding. Another example might be providing a hose of the correct type, size and cleanliness to temporarily reconnect a source fed through an interrupted underground line. The same hose could be used to connect a temporary source.

For those gases made on site (medical air, vacuum, instrument air) a possibility is to spread the risk by using more than one source. As an example, having two smaller, but interconnected vacuum sources reduces the risk if for any reason one goes out of service.

Supply in depth particularly concerns facilities subject to events which may isolate the facility from supplies (e.g. snow, hurricanes). However, it should be a consideration for any facility. Suppliers have their own issues - strikes, accidents, bankruptcy - and preparation for depth of supply should consider these possibilities.

Where risk is relatively high, the facility may wish to proactively upsize their cylinder stocks, provide larger reserve capacity in bulk gas supplies, or add in additional means and locations for connecting temporary sources. This may be a seasonal preparation. In facilities or areas where isolation could be protracted, provision for alternative supply may be desirable, such as providing an on site oxygen concentrator system capable of supplying the facility.

Even some rather simple preparations can usefully be made - for instance a facility might add to their overall checklist for a severe weather event to ensure the bulk tanks are topped up and an extra supply of cylinders is received.

Continuity and resistance are complementary. Continuity assumes the systems will resist and survive the initial event in operational condition, and then we must keep them operating until normal conditions can be resumed. Calculation of time frames is the first item to discuss. How long must the facility be able to operate on it's own? As an example, Florida requires a facility be capable of 72 hours standalone operation without new supply. This can be a design challenge, but is certainly possible if local risks justify it.

During an emergency it may be necessary to reduce usage by limiting gas use to only the most at risk patients. For example it may not be possible to serve patients who receive discretionary oxygen via nasal cannula. During the emergency it may be necessary to preserve the available supply for the emergency room or acute care patients. This kind of carefully calibrated load shedding will of course also influence the size of reserves needed.

Not all areas of the facility merit the same level of concern. ICU and especially NICU areas are so critical that even the briefest outage must be avoided. In these areas, it is becoming more common to see local sources installed that serve only that specific unit. These operate automatically in the event of any hiccough in the supply and ensure there is no interruption for the patients in that unit, but they are not usable in any other part of the facility.

These kind of sources require considerable thought to design and implement correctly. It is important that pressures not fall too low, which tends to rule out standard pressure differential manifold controls. At the same time, it is essential the activation of the auxiliary source be alarmed and the auxiliary source be well monitored.

Oxygen is the most difficult of the gases to replace or substitute, so it deserves the greatest attention. Since liquid oxygen cannot be effectively stored long term, liquid containers are not realistic for a facility isolated from supplies for an extended time. Self sufficiency over long periods would normally be assured by using cylinder oxygen. However, the limited capacity of cylinders presents challenges, especially for a large facility. When seeking to extend the time the facility can stand alone, all of the liquid, cylinder and alternative supplies must be considered and optimized. In the NFPA 99 2018 for the first time guidance is given for implementing an oxygen concentrator as a source for a pipeline system, which opens up a whole list of possible emergency options. Use of concentrators this way has limitations, so it is not something to be done without seeking good advice on the specification, setup and operation.

Substitution generally starts when resistance fails or continuity ends. Substitution will usually be about what happens when all else has failed, but there are circumstances where it may in fact be the easiest solution and can greatly simplify the other plans, so it can usefully be factored into the planning from the start.

Preparing to provide vacuum in an emergency is a case where good preparation can completely eliminate an otherwise daunting challenge. Vacuum can be produced with portable pumps or made from compressed air (or even oxygen in a pinch) using a venturi, so effective (albeit limited) vacuum service can be maintained even without electric power. With vacuum there is also the grisly but

effective last ditch expedient of going preindustrial using hand pumps, turkey basters and absorbent textiles. The precondition in all of these is that the equipment or supplies required must be available, so preplanning is vital.

If medical air is held to be critical, whether to make vacuum or on it's own merit, substituting supply requires some thought. We must have enough capacity and we need to assure the quality of the air supply. Typical alternative supply options for medical air might include cylinders or portable compressors.

So for example, we could provide air using a diesel driven air compressor (it's curious to note that although diesel driven compressors are everywhere, diesel driven vacuum pumps are almost unknown). If we do this, we need to consider how we would hook the portable compressor into the system, and how we would assure the cleanliness and purity of the air. These are points easy to resolve with good preplanning.

Be aware of one little known reality - medical air in cylinders can be hard to obtain, as few gas suppliers maintain any considerable stock. If you consider cylinder air as part of your strategy, make sure that you maintain a stock of these cylinders sufficient for your expected needs, and do not assume they will be available on call from the supplier. Also remember that in an emergency, portable air compressors will rapidly be taken up for other purposes, so one wants to know exactly where to get one of the right type and capacity, and be sure it will be available on the day.

Your suppliers should be consulted and made your partners. The most egregious example is this: every up to date hospital is provided with an Emergency Oxygen Inlet Connection on the outside of the building which exists solely to help with the very problems we are reviewing here. Yet more often than not the day comes when the facility needs to use that connection only to discover the supplier does not have the right equipment to connect to it. It's like a fire truck arriving at the fire without the equipment to connect to the hydrant. In all parts of the emergency plan, the facility and critical suppliers need to agree on what the necessary gear is, who has that gear, where will it be stored, who is trained to access and attach it, and what procedural steps are required.

Generally, with the manufactured gases (nitrous oxide, carbon dioxide, mixtures) the quantities of these which the facility has on hand at the start of the emergency will be all that will be available until the situation returns to normal. Preparation then is simply a matter of ensuring the on hand stock is adequate and the reorder point maintains that coverage. The need for Nitrous Oxide can be largely eliminated by changes in the anesthesia protocol, but carbon dioxide may be more problematic. CO2 is primarily used for insufflation, and critical surgeries could be performed in other more invasive, ways. But CO2 is also used for anaerobic incubators and other laboratory applications which may not have effective substitutes. It's very important to know every application for the gases when planning.

Another example of this may also be seen at in vitro fertilization clinics, some of which rely on liquid nitrogen to maintain their embryo storage. MRI and PET scanners also rely on liquefied cryogens. Liquid nitrogen and liquid helium, like liquid oxygen, have a limited storage life, and there are few or no satisfactory substitutes. Although this is not strictly medical gas in the usual sense, these kind of uses need to be considered as well.

Once the emergency is over many of the more dramatic actions we might have taken during the emergency will need to be reversed. With good preparation, this can be a nonevent, but poor preparation can delay or even prevent restoration of normal service. As an example, if we have prepositioned an auxiliary inlet for the medical air, we can simply restore the normal source, valve off the emergency source, and continue operations without interruption while we remove the temporary equipment. If we have been forced to cut lines and make connections in the throes of the crisis, we may be required to perform a shutdown, test and verify the repairs to restore service.

So in summary, consider:

- What might happen?
- Which systems or supplies could be affected?
- For how long might they be "out of normal"?
- What continuity and substitution strategies will be used?
- Are any necessary auxiliary connection points installed?
- Is the necessary hardware to use them within easy reach?
- If substitution is part of the program, is all required equipment in place?
- Have we closed the circle by detailing how we will restore normal services?
- Is the plan documented and accessible for the people who might need to use it?

Testing the plan, a very critical step but one that rarely is done, is next. If the plan and equipment is never tested, no one actually knows if the plan will work come the day it is needed.

This is obviously the most difficult of all the steps. It involves a lot of time and preparation, and great care needs to be exercised. You will ideally take the normal system off line and simultaneously put the patients onto whatever is your emergency system. This needs to be done for long enough to proof the plan and the equipment. Remember that "restoring" service is also very much part of the drill. The more "full scale" the exercise can be, the more valid the result.

Because there is always risk when you change something, ensuring you can abort the drill and restore "normal" service quickly is essential. That means that the emergency drill should never create a situation which can't be immediately reversed. With systems that have had the benefit of good planning up front, that possibility will never arise because there will be valves and other aids placed to allow the drill to proceed smoothly and without undue risk or any service interruption. Naturally, there will be alarms (that is after all one of the things a drill should be testing), and there may be other minor changes (for instance, system pressure might vary slightly), but the patients should never experience any inconvenience or be placed at any risk.

If after considering your situation, you find a drill cannot be performed without undue risk, then plans should be made for making changes to the system to allow for future drills. You will almost certainly find that these are the same changes that will be required to implement an effective emergency plan anyway.

Whether you can conduct drills or not, it is vital that the emergency equipment that you have stored for emergency use be maintained. Things like regulators and hoses have shelf lives, and if they are not checked and exercised, they may not be usable when you need them most. Consult with the supplier when equipment is put into storage. Include all your emergency equipment in your inventory, inspection and maintenance plans.

Just Chatting: COVID 19 and preparedness

COVID 19 is the first health crisis in history centered on medical gas. The need for oxygen was far outside what anyone had ever anticipated, and facilities found themselves completely unprepared.

Was it a failure of planning? Could such a need have been covered in our emergency plans? In fairness, it would have been a stretch for any facility to have expected these specific circumstances. However, it is very instructive to observe that a facility which had done more general planning for the loss of medical gas supply would have found themselves vastly better prepared to cope with the conditions which did in fact eventuate.

The example that speaks most eloquently is when COVID induced oxygen usage soared, many facilties found their supply could not keep up (storage capacities too small, vaporizers too small, regulators too limited).

A well thought out general strategy for loss of supply would have provided alternative connection points in the system, which would facilitate temporary sources in multiple locations, helping with both supply and pipe sizing limitations.

Many facilties found how valuable the NFPA mandated EOSC connection could be in this context. But a discovery was that the ability to connect sources local to specific units would also prove useful, whether in pandemic or a source failure.

The permit to work system

The NFPA mandate.
Creating a permit to work system.
Record keeping.

NFPA 99 2021

5.1.14.2 Permit-to-Work System

5.1.14.2.1 The Responsible Facility Authority of the health care facility shall develop, maintain and manage a permit to work system ensuring uninterrupted quality, quantity and continuity of supply during all piped medical gas and vacuum system maintenance, repair or construction work.

5.1.14.2.2 The Responsible Facility Authority's plan shall include processes to assure at least the following:

(1) The affected medical staff and facility administration is appropriately in communication prior to any work on piped medical gas and vacuum systems.

(2) Alternative supply or adjustments in patient care arrangements are in place prior to system interruption, including monitoring as appropriate, of the work being performed and the alternative arrangements in use.

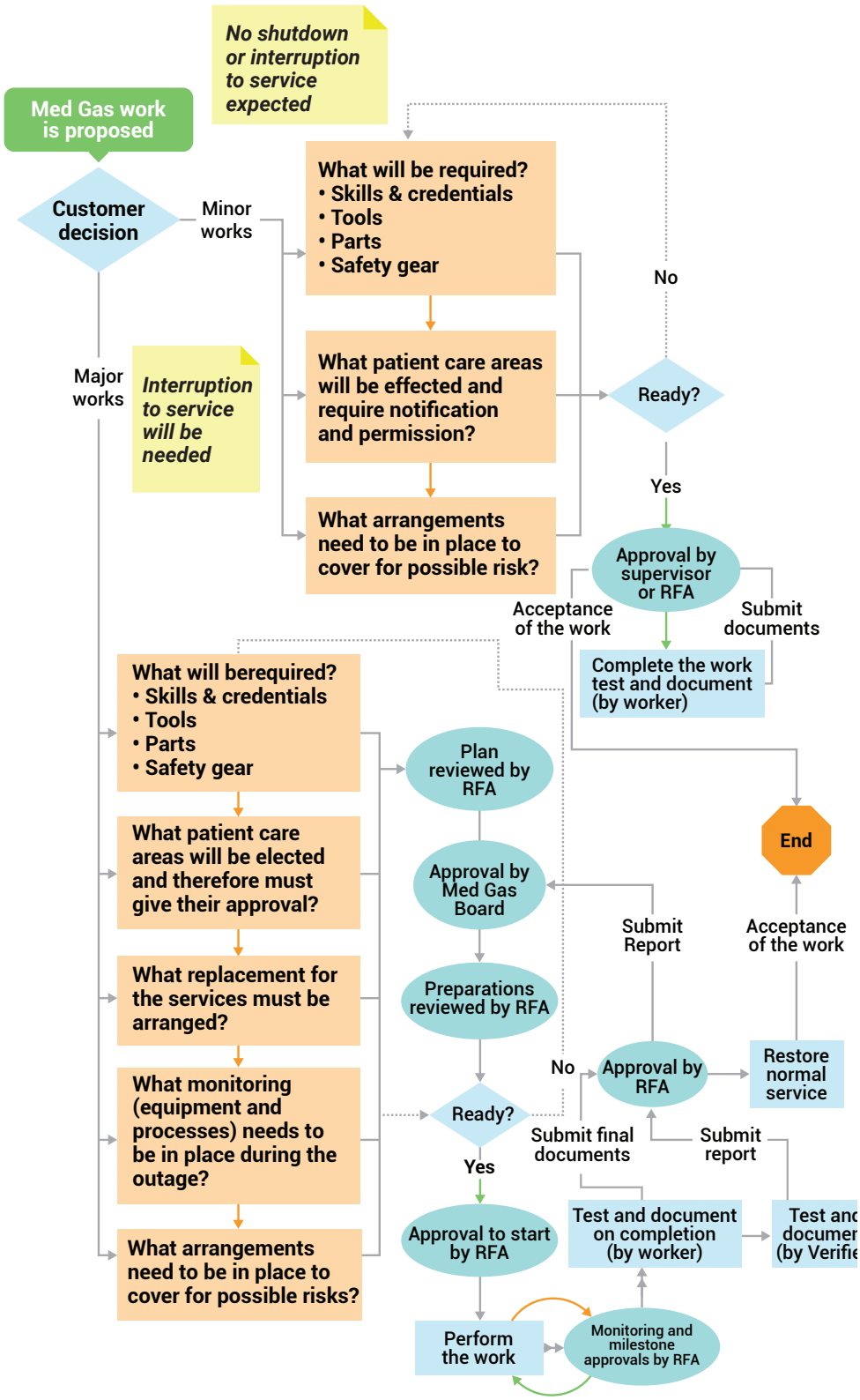
(3) All work on piped medical gas and vacuum systems is performed by competent individuals holding appropriate qualifications for the work.

(4) Procedures for shutdown and restoration of medical gases are described, communicated and observed by all persons working on or with the systems.

(5) Safety procedures are in place and are observed by all persons working on the systems.

(6) This Code is observed in the execution of maintenance, repair or construction procedures.

(7) The affected portion(s) of the systems are correctly tested in accordance with 5.1.12 and 5.1.3 and demonstrated to be acceptable for patient use.



Detail 64
A Permit to Work System

The Permit to Work system as a mandate in the NFPA 99 is entirely new in the 2021 edition of the standard, but it is hardly new as a work practice. Even a basic Lock Out Tag Out system is form of a permit to work system, so most facilities will already have at least parts of such a system in place.

The Permit to Work system as defined in NFPA is of course much more ambitious. Like most of the code, its primary aim is protection of the patient, and the hazard it is most concerned to protect the patient from an unexpected loss of supply caused by construction or other work on a system.

The Permit to Work system is intended to control work on medical gases. It has as its' major objective ensuring that everyone who will be affected by any work on the systems knows what is going to be done, when it will happen, what they should expect and what they need to do to prepare. Ultimately that will ensure interruption of service to patients (where it is necessary) is managed with minimum risk.

With that objective, there are several other objectives that a well designed plan will also cover:

1. Ensure the work is done by persons qualified to do the work.
2. Ensure they have the information and supplies necessary to do the work efficiently and can do it "one and done".
3. Ensure that once the work is done, it is properly tested and documented for future reference.
4. Provide for monitoring (automatically with alarms, etc. And manually through procedures), feedback and communication during the work to ensure it proceeds as planned and expected and everyone with an interest is kept "in the loop".
5. Ensure that service is restored and the "all clear" is given to everyone who needs to know.

Detail 64 outlines how a Permit to Work system might operate. First, note that there are two distinct pathways. One is for minor work which typically will not involve any outages and therefore implies no need for temporary supplies.

Simple operations like this may not even need to directly involve the RFA other than managing the needed documentation. Permit to work approval might be through the regular maintenance supervisor, who will follow an existing SOP and simply provide the prescribed documentation. On this pathway would be all typical inspection and maintenance operations such as filter changes, outlet repairs, calibrations, etc. The "plan" for the operation would be the SOP (see Chapters 5 and 6).

Work that falls along the other pathway is far more critical, and would involve operations that outright require a shutdown or have a strong risk of loss of service. Other considerations would be setting off alarms, reducing system capacity, reducing redundancy, creating a risk of a cross connection, or any operation that turns off a valve or opens a pipe to atmosphere. Examples might include compressor or pump change out, controls work, desiccant replacement, alarm testing, manifold replacement, and almost any form of construction.

These operations need to be more carefully planned, and the RFA would be expected to be involved in creating or at least reviewing a formal plan. They would check that all the necessary considerations had been taken into account and prepared for, and that the people in the affected unit(s) were aware of the situation and prepared for it. They might then present that plan to a Medical Gas committee of the facility for approval.

That Committee would at least include the RFA, representative(s) speaking for clinical staff, for administration, and from maintenance. Many typical operations passing along this pathway would also require a third party verification (NFPA 99 2021 5.1.12.1.3)., and this would be a decision that the RFA would be called upon to take in interpretation of the NFPA 99.

Typically, they would closely supervise the preparations for backfeeding the system, transferring patients onto temporary sources, or clearing patients from the affected areas, depending on the plan.

The actual outage would be the most important event, and the RFA would be expected to be physically present and to give the authorization for closing the valve, shutting down the source or other action that would actually commence the outage. They would of course do this only after physically checking that all the necessary preparations were in place and operating.

If a verifier were used, the RFA would expect to receive the verifiers report along with the documentation from the people doing the work. These would be submitted back to the med gas committee along with any comment from the RFA to close the project. The RFA would oversee the final restoration of normal service and sign off on completion.

The Permit to Work (PtW) system will be written using the same format and techniques as any Standard Operating Procedure. From the NFPA 99, it must include at least all these:

- Purpose of the PtW System
- Audience/Users
- When to Use
- The Procedures to follow
- Documentation required

Sample of a PtW procedure

1.0 Purpose of the PtW system

The Permit to Work system is intended to ensure work done on medical gas or vacuum systems is done:

1. With the full knowledge and confirmed readiness of all persons who will be affected.
2. With all required supplies in place
3. With qualified personnel to perform the work so the work can proceed without delays.
4. With the ability to restore normal service after testing to confirm quality, quantity and continuity of the medical gas and vacuum service.

2.0 Audience/Users

Administration,

Clinicians,

Contractors,

Verifiers,

Maintenance personnel

Suppliers delivering medical gases

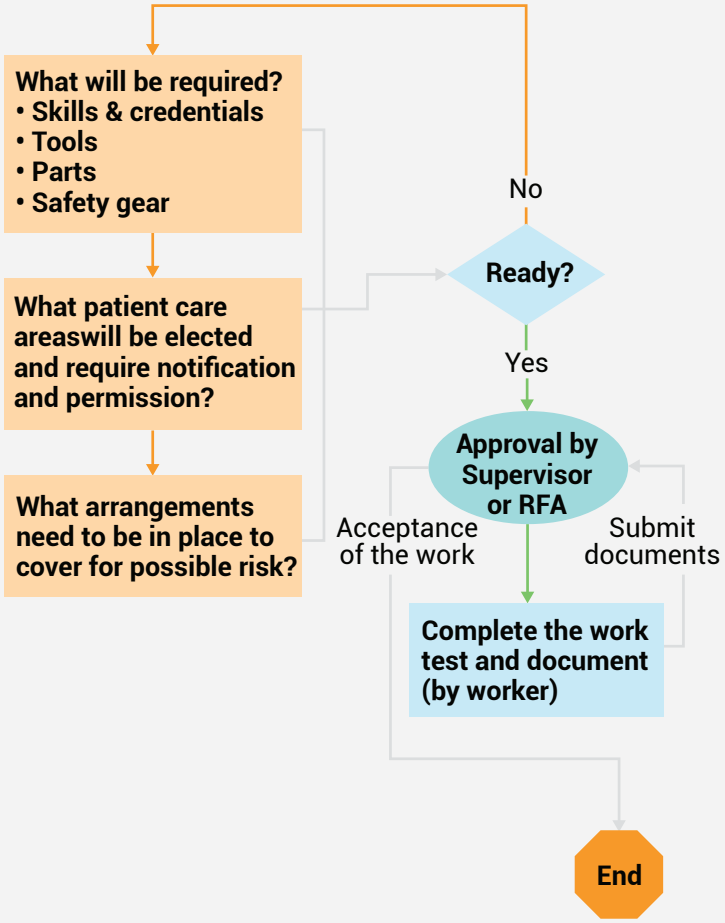
Consultants/architects and Engineers

3.0 When to use

The minor work process (4.1) will be used for all work that does not interrupt service to any patient care area or carry the risk of a larger interruption. Examples would be work on an outlet, standard maintenance or inspection operations described by an existing SOP.

The major work process (4.2) will be used for any work which involves an outage or has a high risk of creating an outage and for all construction work.

4.0 Procedures



4.1 Minor work

4.1.1 Plan

Responsible: Technician

Determine:

1. What is required to do this work (follow the SOP for the procedure involved)
2. What patient care areas will be involved and who are the clinical supervisor(s) for that areas(s) who need to be informed.
3. Is there anything unusual about this process or the area where it is to be done that makes for increased risk?

4.1.2 Prepare

Responsible: Technician

Prepare:

1. Complete and get approvals on a Permit to Work Form.

   SUPERVISOR: the PtW form will require your assistance to complete and obtain necessary approvals.

2. Do you have all your supplies, tools, parts and PPE?
3. Has the clinical supervisor given approval for the work? Are there any preconditions they have set that you need to observe and have you fulfilled those?

4.1.3 Inform

Responsible: Technician

1. Get permission to proceed from your Supervisor.

   SUPERVISOR: if any questions or unusual risks are expected, consult with the RFA prior to granting approval to work.

2. Confirm with the Clinical supervisor (s) that work can begin.

4.1.4 Complete the work

Responsible: Technician

Do the work and perform the testing as required in the SOP for that work.

4.1.5 Document the work

Responsible: Technician and Supervisor

Provide completed documentation to your supervisor.

SUPERVISOR: provide documentation to RFA for inclusion in the permanent records with any comments or observations you wish to add.

4.2 Major work

(NOTE: Major work will usually involve outside contractors, but where it is done internally, replace Contractor with Technician as the responsible person below).

4.2.1 Risk assess

Responsible: RFA, Clinicians and Contractors, others as required

Do a risk assessment on the work to be done.

If specific risks are identified, develop and include a plan to reduce the probability or the severity of the event.

4.2.1 4. Plan

Responsible: RFA and Contractors, others as required

Determine:

1. What is required to do this work
2. What patient care areas will be involved and who are the clinical supervisor(s) for that areas(s)
3. Is it necessary to continue supply to the patient care area(s) during the work? If so, how will this be done?
5. A procedure(s) for monitoring the work as it progresses. This may include automatic means (e.g. alarms) and procedures (e.g. periodic inspections)
6. Testing and Verification plan (see NFPA 99 2021 5.1.12)
7. Complete and obtain approvals on a Permit to Work Form.

4.2.3 Prepare

Responsible: Contractors, Clinicians, others as required

Prepare:

1. confirm the personnel performing the work are correctly qualified/credentialled and acceptable to the RFA, including outside contractors (e.g. the verifier).
2. confirm all supplies, tools, parts and PPE available and on hand.
3. confirm the alternative supply method(s) intended for use during the outage have been tested and that they provide the required quality, quantity and continuity of supply.
4. confirm you are prepared to handle your identified risks.
5. confirm monitoring in place or ready to be put into place.
6. confirm there is an agreed plan or checklist for restoration of service.

4.2.3 Authorize

Responsible: RFA, Medical Gas Committee

Inform:

1. RFA: review the plan and present it to the Medical Gas Committee for approval.
2. RFA: Confirm all involved clinical and engineering personnel are informed and in communication.

4.2.3 Commence the outage

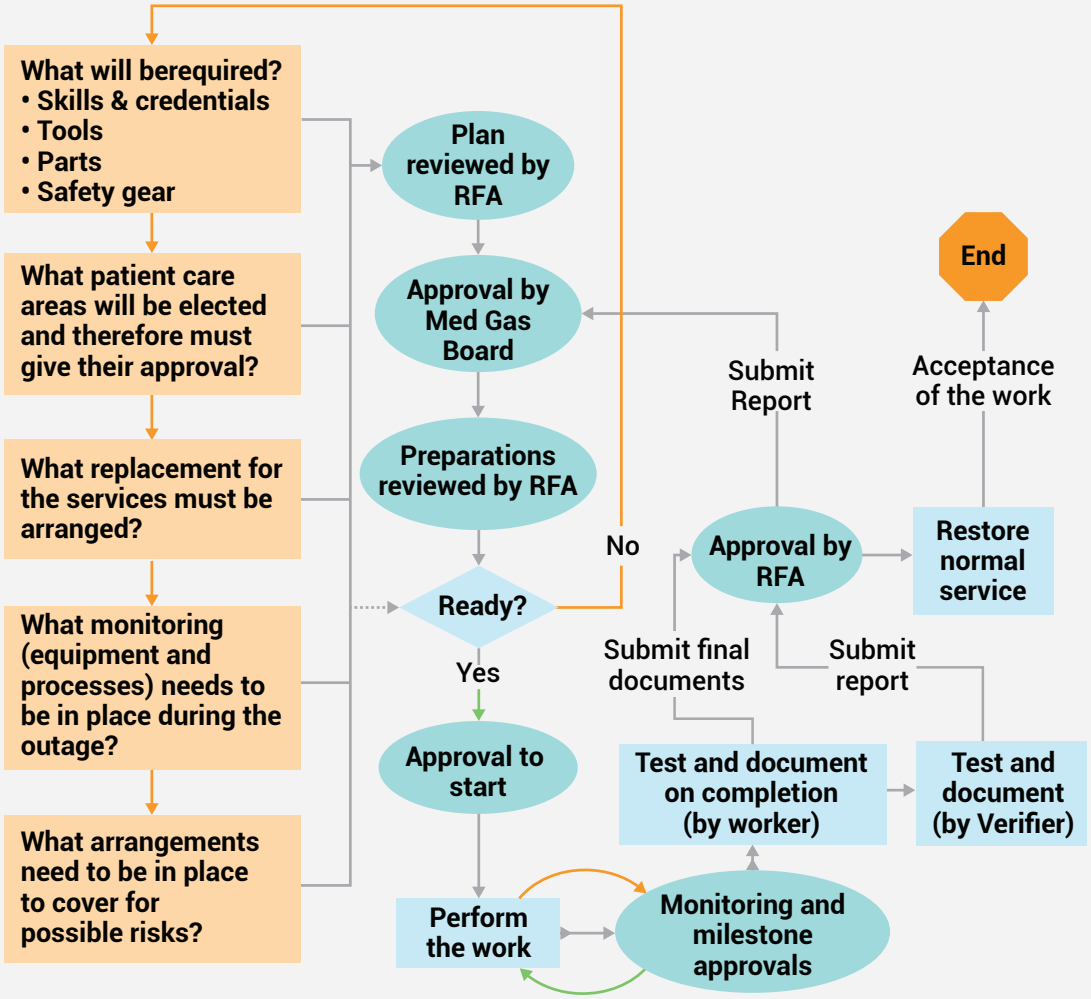
Responsible: RFA

1. RFA: Inspect the worksite and affected areas.
2. RFA: Confirm preparations are complete.
3. RFA: Communicate to involved parties.
4. RFA: Give permission for work to begin (usually in writing) and observe the process.

4.2.4 Complete the work

Responsible: Contractor, RFA

1. As agreed in the monitoring plan and as needed, perform reviews or observations.
2. Provide progress reports for concerned parties as appropriate.
3. Perform the testing as defined in the plan. Provide completed documentation to RFA.



4.2.5 Verify

Responsible: Contractor, RFA, Verifier

1. CONTRACTOR: Have the third party verification performed as required by NFPA 99.
2. VERIFIER: Complete Verification and provide completed documentation to RFA. Separate comments from the verification report for review prior to approval.
3. RFA: Provide reports with your comments and acceptance recommendation to Medical Gas Committee.

4.2.6 Restore service

Responsible: Contractor, RFA

1. RFA: When accepted by Medical Gas Committee, give approval for restoration of service.
2. RFA: Observe restoration of service.
3. Clinical: Confirm service is restored.
4. RFA: File all documents as permanent records.

5.0 Documentation required:

5.1 Minor work

Responsible: Technician, Supervisor

Required documentation is described in the SOP for the work described.

5.2 Major Work

Responsible: Contractor, RFA

The complete documentation package will include at least:

1. drawings, as built, if any piping is added, deleted, or moved.
2. test documents including test results for installer testing (NFPA 99 2021 5.1.12.2 and 5.1.12.3)
3. verifier documentation and test results (NFPA 99 2021 5.1.12.4)
4. comments on the situation as found prior to the work, and as left upon completion of the work, process used and results (for consideration in future improvements).
5. completed approved Permit to Work.

Construction control

The NFPA Mandate
The construction chain.
Concerns particular to construction.
Testing and Verification

NFPA 99 2021

5.1.14.1.2.2 The Responsible Facility Authority shall be responsible for the following:

...

(5) Developing and enforcing permit- to-work rules pertaining to the piped medical gas and vacuum systems and equipment to maintain patient, staff and visitor safety during repair, modification or construction of those systems.

(6) Evaluation and acceptance of the test reports required in accordance with 5.1.12.

Reading that, one might believe that for the RFA, construction is merely an extension of the permit to work system. In reality it is a great deal more.

An active construction project is one of the more complex challenges in the life of an RFA, involving them with a host of people that are not part of the usual round - architects, contractors, inspectors and others, and with questions that they usually don't get asked. Day to day, the RFA is involved with the systems that already exist, construction gets them into the problem of what systems that don't yet exist need to be.

A typical construction chain will go from administration to the architect, from there to the engineer, to the general contractor, then via the mechanical electrical and plumbing (MEP) contractor to the specialist contractor doing medical gases. Variations will involve general contractors who also do the design (design build), equipment planning consultants, and in very large projects, consortia. All have their own politics, power and financial structures and other variables which are outside the scope of this Toolbox but will be essential for the RFA to understand.

The RFA needs to proactively establish a role early in the process. That role should start right with the design, continuing through until (as per the code) they are asked to accept the new work. NFPA 99 establishes them as the essential resource on all matters medical gas, so they should plan to be that essential resource for the design and construction team.

The RFAs involvement in the planning process will certainly include providing essential information. They may be asked about outlet counts and locations, gas services needed, existing equipment specifications, to help decide on valve and alarm locations or many other questions that their experience and records can answer. If allowed, they may take an active role in aspects of compliance and equipment preference, such as the provision of in-line valves for servicing specific equipment, ensuring uniform installation of equipment across the facility, and spare parts control through brand selection. They may be asked to provide information or consult about the location and sizing of existing systems when decisions must be made on sizing and tie-ins of new work.

To be involved in the planning process allows for the elimination of many potential mistakes and future problems, so the opportunity should be actively looked for and taken seriously. If the opportunity arises, the RFA will need to obtain and become familiar with at least the FGI Design and Construction Guidelines (there are different versions for different facility types, see the Bibliography) or the local equivalent in your specific jurisdiction. They will also need to brush up on their NFPA 99 again, particularly those sections on valves (5.1.4), alarms (5.1.9), and manufactured assemblies (5.1.6). These sections are mostly relevant to design and new work, and therefore the average RFA would not need to spend much time with them until a project comes up, but they will guide essential decisions that will be taken in the design process.

It is rare that the RFA will have much say in the selection of contractors, but they are absolutely responsible for assuring the contractor's personnel have the necessary qualifications to do the work (this is part of the Permit to Work rules). Every installer who will touch medical gases will require a 6010 credential, the inspector who will approve the work of the contractor will need a 6020 or 6030 credential, and the verifier will require a 6030 credential at least. These credentials should be collected, reviewed and included with the project records. The RFA may also wish to review the 6010 brazing procedure under which the installers have qualified. Where specialty fittings (e.g. axially swaged elastic preload fittings) or techniques (e.g. orbital welding) are used, they may ask for the contractor to demonstrate their people are trained in that specific process.

Just Chatting: About Verifiers

Unfortunately, med gas verification is not generally regulated. Under the NFPA 99, a Verifier simply needs to have a 6030 credential. They do not have to have insurance, or to calibrate their test equipment, or to do any continuing education, etc. While these are things that one would expect of a professional in such a sensitive position, they are simply nowhere required at this time.

Naturally, the contractor is likely to hire the Verifier based on lowest cost, and given this reality, that may not be in the facility's best interest.

The RFA must pay particular attention to the qualifications of the Verifier if they are to ensure that their facility's expectations are met. Fortunately the verifiers themselves are aware of this concern. To help deal with it, their professional organization (MGPHO) has developed and enforces a more rigorous credential beyond the 6030, called the Credentialled Medical Gas Verifier (CMGV).

The CMGV credential provides some of the things that you as an RFA would expect from your Verifier - valid insurance, periodic examination of equipment, as well as a regular opportunity for some continuing education and additional testing. While far from perfect, a CMGV credential is a consideration when you're the one everyone is looking to for assurance that it's all right.

They should take particular interest in the qualifications of the Verifier. The Verifier will be the person who is most likely to find the more subtle mistakes, and therefore is the RFA's best ally in protecting the patient. The wise RFA will make sure the Verifier, whether hired by the contractor or by the facility itself, is the best qualified and most trustworthy they can find. (see the sidebar on Verifiers).

A wise RFA will make it their business to observe as much of the construction process as they can. They will become familiar with where things are and how they are laid out. No as-built drawing can ever capture all the nuances that a simple walk through will reveal. The RFA also may be able to spot problems while they are easy and inexpensive to correct, which is money saved for the contractor and headache avoided for the maintenance staff. A wise contractor will encourage this and actively participate in these walkthroughs.

The most critical and central role of the RFA is to receive, validate and approve the final reports on the installation from the contractor (see NFPA 99 2021 5.1.12.2) and inspector (see NFPA 99 2021 5.1.12.3) and the verification report from the verifier (see NFPA 99 2021 5.1.12.4).

It is essential to understand that it is NOT the role of the Verifier to pass or fail the systems. NFPA places the responsibility for determining if the Verifier's results will allow the system to be used with patients squarely on the RFA. The Verifier only provides the necessary information to allow the RFA to do that. An attentive Verifier will usually have some comments, which may be simple observations, disputes over code interpretation, or outright violations of the code. It is these comments where the most important information is often found or summarized.

The RFA should insist on receiving and approving the as-built drawings from the contractor. It is astonishing how rare it is to encounter a facility with accurate as built drawings, and when climbing into a ceiling to trace piping is a major undertaking, these documents are more important than ever. Too often the requirement for these drawings is overlooked in the rush to close out a job, and if no one pays attention, they never get done. The RFA can do themselves and the maintenance department a huge service by being the one who pays attention.

The RFA often will become the expert to whom all the parties in a dispute turn. They will be asked to decide if work must be redone or if a reported problem is insignificant to the functioning of the system within the intent of the Code (see NFPA 99 2021 1.3 and 1.4). It can be a heavy responsibility. Any decision and the logic used to reach that conclusion should be carefully documented.

With entirely new work, the Permit to Work (PtW) system will not have a great deal of impact. Afterall, the systems are all new and there is not much need for that specific type of control. In renovation work the PtW system becomes very essential, as the risk to patients of an inadvertent cutoff of supply or accidental crisis (e.g. the drywall screw through the pipeline) is ever present. These are exactly the problems that the PtW system is intended to cover.

The PtW system will of course always come into play when there is a tie in or other interface between new and existing systems. The contractor must be advised early in the process of the existence of the system and of their responsibility under it. The RFA will need to be mindful that they need to manage that when the time comes.

Just Chatting: Interpretation of the Code

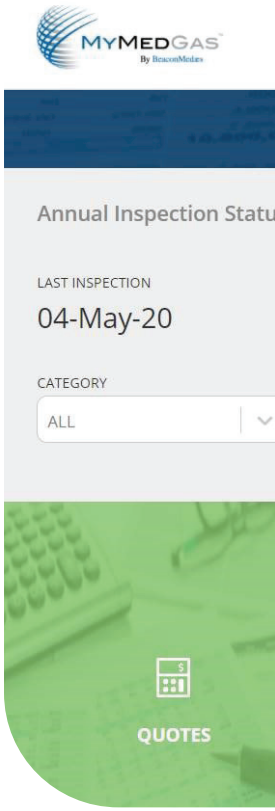
One of the challenging roles given to the RFA in NFPA 99 5.1.14.1.3.1 is to interpret the Code. This can be the thorniest challenge an RFA will face, and is likely to get worse with experience as others come to respect the RFA for their knowledge.

This is where a wide network of other professionals will prove invaluable, and the wise RFA is advised to seek every opportunity to discuss issues with their peers to understand how others have approached similar problems. Consensus is rarely the solution to an interpretation question, but broad experience can often help argue one.

MyMedGas – The Perfect Resource for the RFA

How MyMedGas helps the RFA

Healthcare facility managers, responsible facility authorities (RFA), risk managers and hospital administrators need to ensure the piped medical gas systems in their facilities are in full compliance to the local standards. **MyMedGas** by **BeaconMedaes** allows you to manage piped medical and laboratory gas compliance all in one central location. Our easy-to-use online cloud platform includes inventory asset management, monitoring of equipment, report of equipment, training (both credentialed and topical courses), and preventative maintenance service scheduling. Now with **MyMedGas** by **BeaconMedaes**, you have the right tool to easily manage everything in your medgas world.



Training

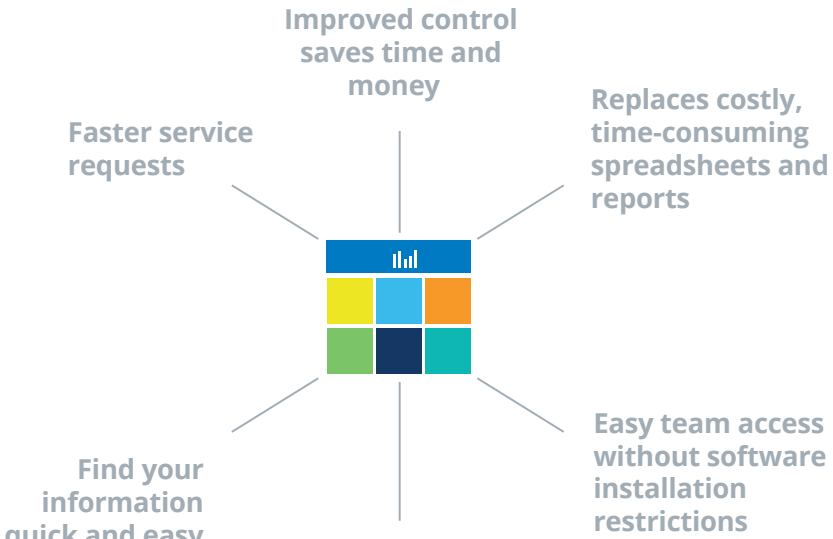
Our training helps prepare you for the role of RFA.

- ASSE 6040 Medical gas maintenance
- ASSE 6000 Series refresher (re-certification)
- ASSE 6005 Medical gas generalist
- ASSE 6020 Medical gas inspector
- ASSE 6010 Medical gas installer
- Medical gas basic series
- Specific medical gas equipment training

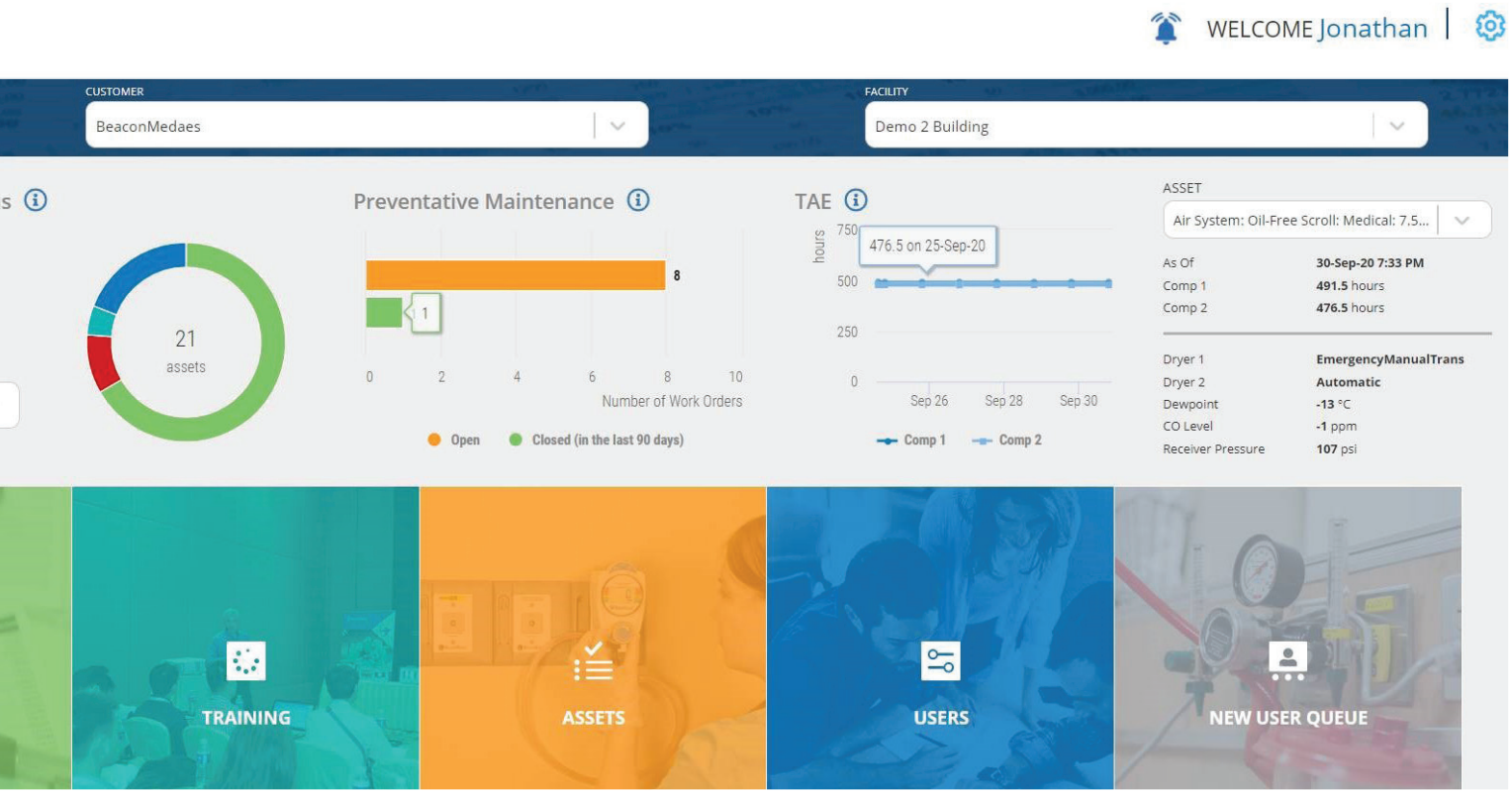
Asset management

Complete asset lifecycle tracking

A complete asset management solution that includes a detailed history log for each asset – starting from installation all the way through replacement



Platform complies to latest data protection regulations



Reporting dashboard

Information management dashboard

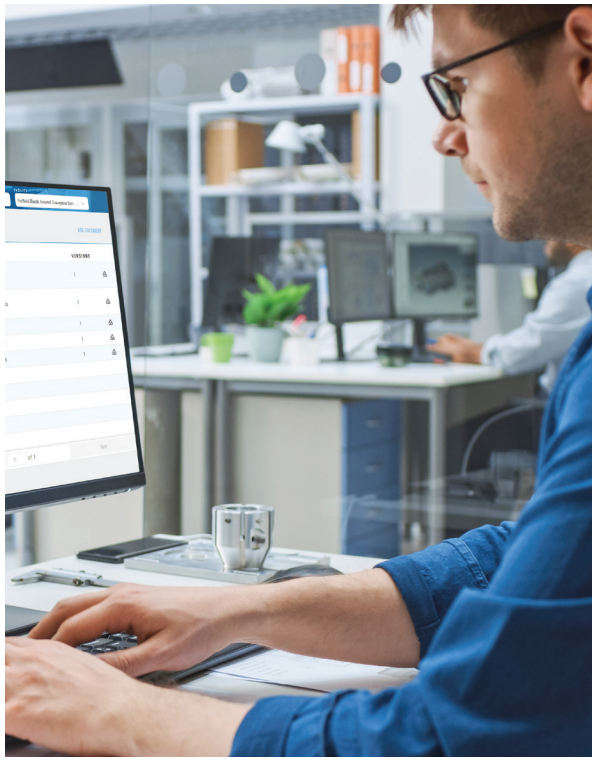
Visually tracks, analyzes and displays key performance indicators **bringing intelligence to you**

Helps you make informed and faster decisions

Offers automatic email stats to team members within your facility

Document library

Easy access -
Keep all critical compliance reports in one place



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Annexes

Annex I

The HTM 02-01, Part B in the UK - the process at work

While the RFA is new to the NFPA world, it is a well established part of practice in the United Kingdom under the HTM 02-01 standard that was originally published in 2006. Since that time, every facility complying with that standard is required to have on staff or available an "Authorized Person", a role which is functionally equivalent to the RFA in the NFPA.

Where HTM is most interesting for the facility looking to put an RFA in place is the governance structure the HTM creates for the medical gas systems overall. That structure manages the work of the AP and provide a way to resolve most of the problems an RFA will inevitably run into. Examples of these will include questions like:

- When a major shutdown is proposed, who will review and approve the plan besides the RFA? It would require either extraordinary confidence or plain foolishness for the facility to allow such an event to proceed on the simple say so of one person.
- Who manages the RFA? Depending on the responsibilities assigned, the RFA could end up as either a quite senior position in the facilities group or at a lower supervisor level. Yet they have a very specialized remit with implications for every patient in the building, the facility's reputation, and accreditation. While on standard H.R. matters it's easy enough to fit them into the hierarchy, on questions within their specialization it makes sense to involve a range of interested parties.
- If the RFA believes a need to be critical (for example a need to replace a central supply system like the medical air plant) are they expected to argue that to the CFO, Senior management and the Board against all the other competing interests for capital or operating monies? Should other interested parties also evaluate the situation and weigh in on the priority?

Where NFPA limits itself to the RFA role itself, HTM discusses these questions of governance and also requires an entire medical gas management structure. In this respect the HTM program is more matured and complete than the NFPA. It calls for and defines the involvement of:

- The "Executive Manager" (CEO);
- An "Estates/Operations Manager" (C-suite Head of Facilities);
- An "Authorizing Engineer" (a role with no equivalent in U.S. hospital systems. As outlined in the HTM this role would typically be split between the Head of Operations, the engineering entity that would handle design and construction, the Maintenance Supervisor/Facilities Manager and the contract Verifier);
- A "Quality Controller", which for most US facilities would be a contracted Verifier;
- Various "Competent Persons" (mechanics and installers);
- A "Designated Medical or Nursing Officer" (medical staff)

The HTM places some of these persons onto a regular "medical gas committee" which holds the ultimate authority for important decisions, such as approval of policy documents. Thus, it creates a clear hierarchy of responsibilities and authority. The structure underpins the standard but also provides controls over the actions of the AP and involvement of the essential stakeholders in the processes.

The HTM requires a specific "medical gas operational program" (and gives an example in Appendix B) which is of course the top level stuff that the RFA will need to do their job but which they usually would not be writing by themselves

Most of the requirements in HTM have their analogues in the NFPA:

Approximate equivalent sections of the standards	
HTM 02-01 Part B	**NFPA 99, 2021**
Operational Policy Chapter 5	5.1.14.1
Permit to Work System Chapter 6	5.1.14.1.2.2 (2)
Training Chapter 7	5.1.14.4.2.5 (A) (see also ASSE 6000)
Cylinder management Chapter 8	Chapter 11
General Safety Chapter 9	5.1.14.2.1 (5), 5.1.14.1.2.2.(4)
Maintenance Chapter 10	5.1.14.1.2.2.(6), 5.1.14.4.2.4 (See also ASSE 6000, Annex D)

In respect of credentialing, the requirements and curricula of study for all the necessary credentials are contained within the HTM document. HTM also details the qualifications and in some cases the training appropriate to all of the several roles it describes, down to and including the person who changes and transports gas cylinders. The NFPA instead references the separate ASSE 6000 document. The ASSE does not cover all the same roles (it has nothing on Medical personnel, Quality controllers or "porters" (the people who handle cylinders)), but covers some the HTM does not, like the Medical Gas Designer. Both cover the verifier but under different names (Verifier under NFPA /ASSE and a combination of Authorizing Engineer and Quality Controller under HTM)

While NFPA allows an RFA to hold essentially any ASSE credential, the HTM is more specific in the credential required for an AP. A comparison of the various 6000 Series qualifications with the HTM AP would argue that the ASSE 6040 is the most equivalent credential.

In the HTM, cylinder management and handling processes are provided for in great detail. Chapter 11 of the NFPA document covers some of the same ground, but is not specifically directed to any single individual and requires no training or credential as such. The HTM requires training and a certification for this "porter" role.

The HTM provides several checklists and has a group of interesting appendices. These will provide anyone undertaking development of a RFA program with some starting points and general guides on points NFPA does not mention. In particular, HTM Chapter 5, Appendix A and B is how to prepare a Medical Gas Operational Policy, and Appendix D is instructions on work with Vacuum and AGS systems (WAGD in NFPA).

We recommend that anyone looking at appointing an RFA to comply with the new NFPA or simply out to improve their own control over their medical gas operations, improving the resilience of their systems, or discharging their obligation under NFPA 99 for inspection, maintenance and emergency plans would benefit from a look at the HTM.

One of the best things about the HTM document - it is available as a free download from:

https://www.gov.uk/government/publications/

Search for HTM 02-01, and you will see Parts A, B and the Dental facilities HTM as well. It is Part B which contains all the material on the operational program and the AP.

Annex II

How to perform a risk analysis

The principle behind risk analysis and mitigation is quite simple at heart. You see something that could go wrong, determine what could prevent that, and by doing it, you prevent the original problem. It's something any thoughtful person will do whenever they are taking on a task that might go wrong on them. You set up a ladder but see it's tilted. That means you could fall over and hurt yourself, so you get a piece of wood and level the ladder before you climb up.

Of course, the RFAs' world is a bit more complex, but the basic idea is the same. We are going to do more speculating and a lot more documenting, but when we are done we will simply have identified the possible problems, and identified plans and actions to deal with them.

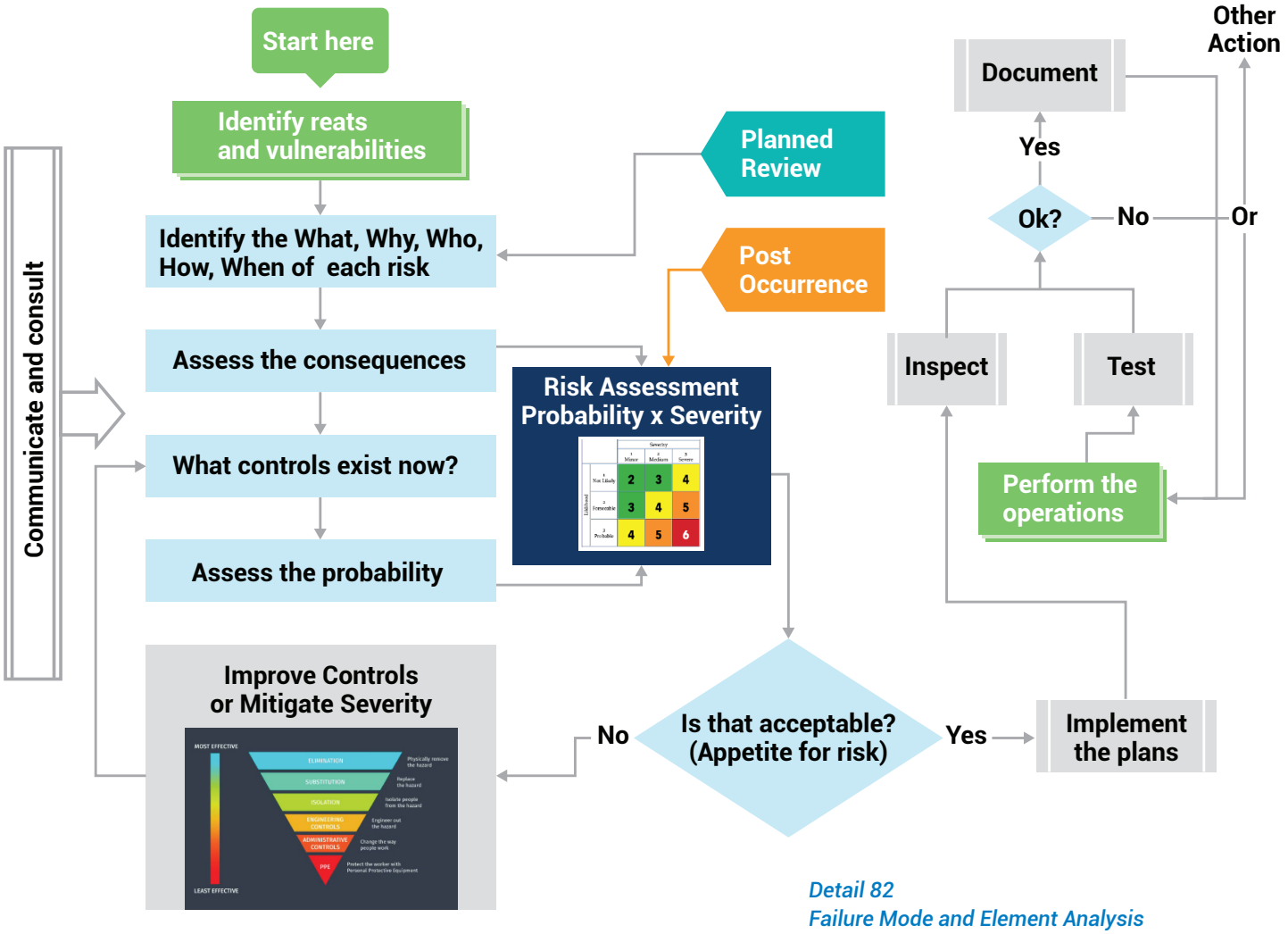
The methods for doing this are well documented and should be easily comprehensible by any RFA. Detail 82 is a bit more complete model of the process overall.

This model process for developing a risk assessment is called a Failure Mode and Element Analysis (FMEA) (there are other models will get you to the same place).

There are six steps in an FMEA. Your inventory will be the starting point:

1. Decide what can go wrong. We are particularly looking for events which would affect patients - events that would break the first or second rules of medical gases. This will need to be done for each system and each piece of equipment in that system. Some will be considered only once, like terminal units (because the same basic problems, remedies and preventative measures will be probably be used for an outlet in an oxygen system as for an outlet in medical air). Other events will need to be considered layer by layer, including system level problems, component level problems and even problems entirely external to the system. For example, with a medical air system we will need to consider the room it is in, the system overall, major subsystems like the supply sources and down to individual components like the compressor, dew point monitor and pressure regulators.

   On a first pass, one can get quite carried away with this, identifying potential failures down to a level of detail which makes the list unmanageable, or including possibilities so remote that considering them gets to be comical (zombie apocalypse, anyone?). So once a list is constructed, a first screen must be applied. This



Detail 82
Failure Mode and Element Analysis

first screen would be the estimated probability of this event. If the event is conceivable with just a little bit of Murphy's Law, then it should be included. If it would require an event so unusual or a chain of events so improbable as to challenge the imagination, then set it aside and don't consider it for the next step.

A typical example is seismic risk. Everywhere on earth has some seismic risk, so in theory this should always appear on every list. However, if there has never been an earthquake of any consequence at your location in recorded history, and you are not located in an area with known seismic risk, this one can probably be set aside and your energy put toward more likely events.

Let's use an example. Assuming you have an air system which is already compliant with NFPA 99, 2021, we will construct this scenario:

What happens (the event)
Med Air: high dew point

2. Consider what that event would mean. To say that another way, if this occurred, what would be the symptoms you would expect to develop? This will help with prioritization later.

What happens	The consequence
Med Air: high dew point	Water appears at the outlets
	Damage to respiratory equipment
	Patients drown

3. Consider how this could happen. What could be the direct cause(s) of the particular event you have identified? Naturally, a given problem could have many possible causes, each of which should be considered separately.

What happens	How could this happen?
Med Air: high dew point	Dryer valved off (bypassed)
	Dryer failure
	Compressor room too hot
	System overdrawn

In these analysis, avoid being either too generic or overly "micro". Broad and generic events like "system failure" should always be broken down. In the example above, we have listed "dryer failure" as a possible cause. While true, this is not very useful in figuring out what to do to prevent it, so let's think a bit harder and be more specific:

What happens	How could this happen?
Med Air: high dew point	Dryer valved off (bypassed)
	Dryer failure:
	• switching valve failure
	• desiccant ruined
	• dryer not powered
	Compressor room too hot
	System overdrawn

The more specific list allows us to develop specific actions. We can look for these conditions in our inspections and take action through maintenance.

4. Weight the risk. Traditionally, two measures are applied: How likely is this event (likelihood), and how bad would it be if it occurred (severity). A simple matrix can be built to compare various events.

Likelihood	Severity: 1 Minor	Severity: 2 Medium	Severity: 3 Severe
1 Not Likely	2	3	4
2 Foreseeable	3	4	5
3 Probable	4	5	6

We have used a very simple 3x3 matrix, but you will see 5x5, 10x10 and other more complex versions of this. Of course, a larger matrix allows for finer distinctions, but also adds to the complexity of the matrix and makes the evaluation process slower and more complex. Simplicity is best, particularly if this is your first time doing this. You can use a larger matrix later if it makes sense or you need more gradations.

To use the matrix, you must set up a guideline to the values so you can consistently weigh one possibility against another. It is important to use this in a consistent manner. Ours is:

Severity

- Minor - Procedures would continue with no risk to patients,
- Medium - Cancellation of procedures with possible risk to patients,
- Severe - Termination of supply with definite risk to patients.

Likelihood

- Not likely,
- Foreseeable with just a little bad luck,
- Probable.

Then, for each of the specific causes, assess the liklihood and the severity of that event, and plot those on the matrix.

Experience pays here - any event which you know has actually happened in your facility will of course be Foreseeable or Probable. You will also know what havoc it brought with it, so you can accurately score it on the severity scale! Events which have never occurred will require some thought.

Ideally, this will be approached in two passes. First pass, look at each of the causes, assuming you did nothing to prevent it. Then, consider what you can do to prevent or manage the problem, and reevaluate. For our scenario, first pass:

How could this happen?			Severity			Comment
dryer valved in bypass	Likelihood	1			4	Maintenance error, unlikely but serious
		2				
		3				
switching valve failure	Likelihood	1				will happen eventually if not maintained/replaced
		2				
		3			6	
desiccant ruined / worn out	Likelihood	1				will happen eventually if not maintained/replaced
		2				
		3			6	
dryer not powered	Likelihood	1			4	Maintenance error or electrical fault
		2				
		3				
Compressor room too hot	Likelihood	1				room ventilation needs to be inspected and maintained
		2		4		
		3				
System overdrawn	Likelihood	1		3		likely only if system is added onto or medical practice changes occur
		2				
		3				

5. Not all events are equally concerning or deserve equal consideration, as our scoring system shows. Events which are highly likely or have very severe consequences (in the red or orange zones) must be considered particularly serious and need to have action taken or plans made. Events with low scores (in the green zones) can probably be set aside until higher priorities are resolved.

Consider next what you can do to ensure that this event does not happen. Most of the planned actions will of course be good maintenance, periodic testing, monitoring, etc. That is exactly what you are looking for, because from this you can construct a meaningful action plan.

If total prevention is not realistic (which is usually true) then consider that if the event does happen, how can you ensure that neither of the two rules of medical gas gets violated, and equally, that no one gets injured. Remember, you are looking for actions that you can take.

From most to least effective, the general risk control hierarchy is:

1st and Best - Elimination - Eliminating the possibility of the event completely by removing the device or stopping the practice. Usually tough to do with medical gases, but certainly worth considering. In our scenario, we could eliminate dryers by using air from cylinders or install nitrogen/oxygen blenders. We could buy all clinical equipment with on board compressors and shut down the central medical air system (probably all bad ideas, but you see that it is possible).

2nd - Substitution - Replacing the system, component or method with a different one with less or no risk of this event. In our scenario, we could perhaps use a different dryer type.

3rd - Isolation - Guard against the event with a physical barrier. Ideally, the barrier prevents the problem from happening but may also provide that if it does occur, no one will be injured. Things like locks, guards and heat

shields are there for this reason. In our example, installing water separators and drains at the air outlets would not prevent water from forming, but might act to prevent the water from getting to the patients and therapy equipment.

4th - Engineering controls - altering the devices or practices to cover the risk. This is the principle behind redundancy. Having redundant dryers and a dew point alarm are both in this class.

5th - Administrative controls - Warning signs are the obvious example. In our air dryer scenario, if you assume you can't stop the water from forming, you might put signs at every outlet warning the medical staff that water may be in the air and requiring them to purge the outlet before use.

6th and least effective - Personal protective equipment (PPE). Since we are concerned first and foremost with the patients, this is not usually an option, but it may be relevant to the people dealing with the equipment. However, in our scenario there is no way to protect the patient using PPE.

Obviously, many of these ideas are impractical and some are simply silly, but you can see that there are almost always options that we can consider as part of a risk mitigation plan.

Returning to our scenario, we might assess the following actions make sense:

How could this happen?	What can be done to prevent this?
High dew point (all causes)	• Maintain dew point monitor; • Respond to alarms; • Keep the second dryer ready to use.
Dryer valved off (bypassed)	• Test operation after maintenance is performed; • Warning label on the bypass valves.
switching valve failure	Maintain/replace per mfr. Instructions.
desiccant ruined	Maintain/replace per mfr. Instructions.
dryer not powered	Check operation during rounds.
Compressor room too hot	• Inspect and maintain room ventilating fans; • Check temperature during rounds.

Circle back now to the risk matrix. If you do these actions, how does the risk look now? If your actions are good ones, then the risk should be reduced, ideally into the green area. That can be shown on the matrix: (Check next page for the matrix)

We have through our various actions made it less likely that the event would occur, and also reduced the severity if it did occur because we would discover the problem quickly and be able to quickly correct for it thanks to redundancy (a second dryer on standby) and monitoring (the mandatory dew point monitor) built into the system.

Now we can develop a list of actions. These will naturally fall into three classes:

1. System changes that need to be made
2. Maintenance activities
3. Inspections

From our scenario, these lists might look like:

System changes:

- Add warning labels to dryer bypass valves

Maintenance activities

- Dew point monitor maintenance (see manual)
- Confirm second dryer is operational by rotation
- Dryer maintenance (including switching valves and desiccant replacement)

Inspections:

Add to rounds checklist:

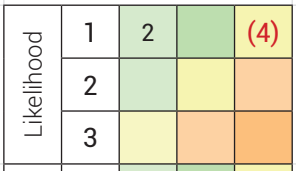
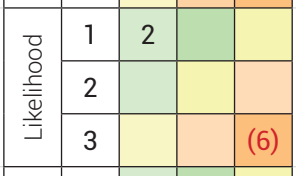
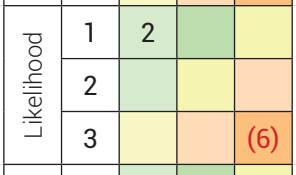
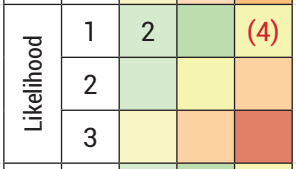
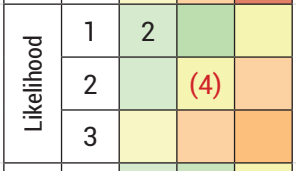
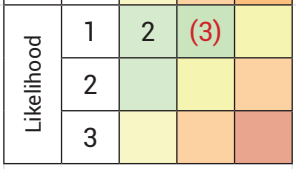
- Compressor room temperature check
- Dryer operation (towers are switching)
- Dew point alarm is not on
- System low reserve capacity alarm is not on
- General system operation (on/off compressor operation)

6. Armed with these lists, you can begin to assemble your plans.

Making system changes will always be a budget question. Obviously, you should do these changes as soon as possible and you will of course do the simple and inexpensive ones. Generally you will have no choice on the high risk ones. But most facilities cannot rush out and do every one of them because they can be too costly. In that case, there will need to be a long term plan for updates and improvements. The analysis will let you decide the priorities for presentation to your CFO and management.

The Maintenance activities list will for the basis for your maintenance plan (see Chapter 6).

The Inspections list will be the starting point for your Inspections plan (see Chapter 5)

How could this happen?	Severity	Actions
High dew point (all causes)		• Maintain dew point monitor. • Respond to alarms. • Keep the second dryer ready to use.
Dryer valved off (bypassed)		Test operation after maintenance is performed
Switching valve failure		Maintain/replace per mfr. Instructions
Desiccant ruined		Maintain/replace per mfr. Instructions
dryer not powered		Observe system operation during rounds
Compressor room too hot		• Inspect and maintain room ventilating fans • Check temperature during rounds
System overdrawn		• Test prior to any new work being commissioned; • Observe system operation during rounds • Monitor and respond to reserve capacity low alarm

Annex III

Forms

The forms in this Annex have been used elsewhere in the document and are provided here to make it easy to copy or transcribe them for your own use.

Forms provided:

Permit to work on medical gases

Permit #: Issue Date: ____ /____ / _____

The following work is to be completed:

The Contractor performing the work is:

The work will take place starting approximately ____:___ hours on ____ /____ / _____
and completing approximately ____:___ hours on ____ /____ / _____

This work:

❒ WILL involve a planned outage.

❒ WILL NOT involve a planned outage, but has been risk assessed to have a reasonable probability for an unplanned outage.

For either of the above, summarize the continuity plan:

❒ WILL NOT involve a planned outage.

Contacts

The following are to be continuously present or can be reached in the event of need during the work:

RFA:	Cell (_____)- _____ - _____
Clinical:	Cell (_____)- _____ - _____
Maintenance:	Cell (_____)- _____ - _____
Administration:	Cell (_____)- _____ - _____
Contractor/Tech.	Cell (_____)- _____ - _____
Verifier	Cell (_____)- _____ - _____
_____	Cell (_____)- _____ - _____

Approvals:

I understand the project, the planning, and the preparations required of the department(s) I represent. I will be prepared as per the plan for the work to begin as scheduled.

Administration: _____

Clinical: _____

RFA: _____

Maintenance: _____

Contractor/Technician: _____

I consider all preparations to be in place and am ready to commence the work described:

Contractor/Technician: _____ at _____:____ hours on _____ /_____ / _____

Having examined the preparations, I authorize the commencement of the work described:

RFA: _____ at _____:____ hours on _____ /_____ / _____

All work and required testing is complete:

Contractor/Technician: _____ at _____:____ hours on _____ /_____ / _____

All required installer testing is complete and satisfactory:

Inspector: _____ _____ /_____ / _____

Verifier testing is complete as will be described in the final Verification Report. Any discrepancies have been noted and provided in writing:

Verifier: _____ _____ /_____ / _____

Having interviewed the Installer and Verifier and conducted my own review(s)as necessary, I accept the work described and authorise it to be placed into service

RFA:_____ _____ /_____ / _____

Clinical: _____ _____ /_____ / _____

Medical Gas FMEA (Failure Mode and Effect Analysis)

The failure	The consequence	How could this happen?	Risk Matrix	Prevention Plan	Inspection Plan	Notes
#			Severity 1 2 3 Likelihood 1 2 3			
Code Ref:						
#			Severity 1 2 3 Likelihood 1 2 3			
Code Ref:						
#			Severity 1 2 3 Likelihood 1 2 3			
Code Ref:						

Maintenance Planning Form

FMEA reference	Operation	Frequency	Tools	Parts	Skills needed	Training requirement

Maintenance record

Machine details	Technician
System: Location:	Name: ID#:

Operation	Completed (Date/time)	Comments	Parts used
	___/___/_____ Start: ___:___ Finish: ___:___		☐ ☐ ☐ ☐ ☐
	___/___/_____ Start: ___:___ Finish: ___:___		☐ ☐ ☐ ☐ ☐
	___/___/_____ Start: ___:___ Finish: ___:___		☐ ☐ ☐ ☐ ☐
	___/___/_____ Start: ___:___ Finish: ___:___		☐ ☐ ☐ ☐ ☐
	___/___/_____ Start: ___:___ Finish: ___:___		☐ ☐ ☐ ☐ ☐
	___/___/_____ Start: ___:___ Finish: ___:___		☐ ☐ ☐ ☐ ☐
	___/___/_____ Start: ___:___ Finish: ___:___		☐ ☐ ☐ ☐ ☐

Annex IV

A sample procedure

Testing vacuum outlets
for flow and general condition

To be used for periodic testing of vacuum terminals and when terminals are cleaned or rebuilt.

Applies to all vacuum and WAGD terminals In any patient care area.

Rev.	Date	Approval
1	11/2020	

Sample Procedure - Page 1

Safety precautions and Pre-start preparation

Hazards and cautions

BIOHAZARD: Vacuum equipment and Terminals can be contaminated and biohazardous

USE PPE: Plastic gloves, goggles or faceshields

SHARPS: Edges of plates, screws and internal parts can have sharp edges or metal shavings

USE PPE: Abrasion protective gloves if disassembling terminals for repair

Preparation required

None

Tools, parts and supplies required

	PPE
	Medical Staff with you or within call in any room with patients
	Flowrig with correct adapter(s) (see drawing p. 6)
	Clipboard, test record form(s) and pen

Permit to work process requirements

1. Obtain verbal overall approval from Medical Gas Responsible Facility Authority
2. Obtain verbal approval from floor personnel in area(s) where you will be testing

Procedure

Testing objective: to demonstrate that a vacuum inlet is flowing within specification:

three (3) scfm with vacuum of 12 inHgV or better.

Performing the test (how-to);

1. Assemble the flowrig as illustrated on page 6;
2. Make sure plug valve is closed;
3. Insert flowrig in outlet until it is engaged and locked.
   Check it is engaged and locked by pulling back on the flowrig. If it is locked, it will resist being pulled out of the terminal. If it is not engaged or the lock is not working you will be able to remove the flowrig;
4. If the lock is OK, mark the "√" in the Lock column. If it needs repair, and if time permits and the repair is simple, you can repair and retest. Put only the final test on the Form, and note "Repaired" in the Notes column. If the lock cannot be immediately repaired, mark the "X" on the testing form (page 5);
5. Read the guage and write the reading on the testing form as ***"static vacuum level"*** (note that the vacuum may go up and down as the pump cycles. This is normal and you should take the vacuum reading just before you begin step 6);

6. Open the valve slowly, while watching the vacuum guage. When the gauge reads 12 inHg, read the flow from the flowtube and put this on the form as ***"flow at 12"Hg"***;

7. Open the plug valve completely. Read the flow. Put this on the form as ***"full flow"***;

8. Close valve and remove flow rig from terminal;

9. Note any deficiencies or other notes in the ***"Notes"*** space on the form.

Documentation

Use test reporting form page 5 (copy as needed)

Testing and repairs can be performed by any 6040.
No pre-approvals are required before testing.

If any terminals require repair:

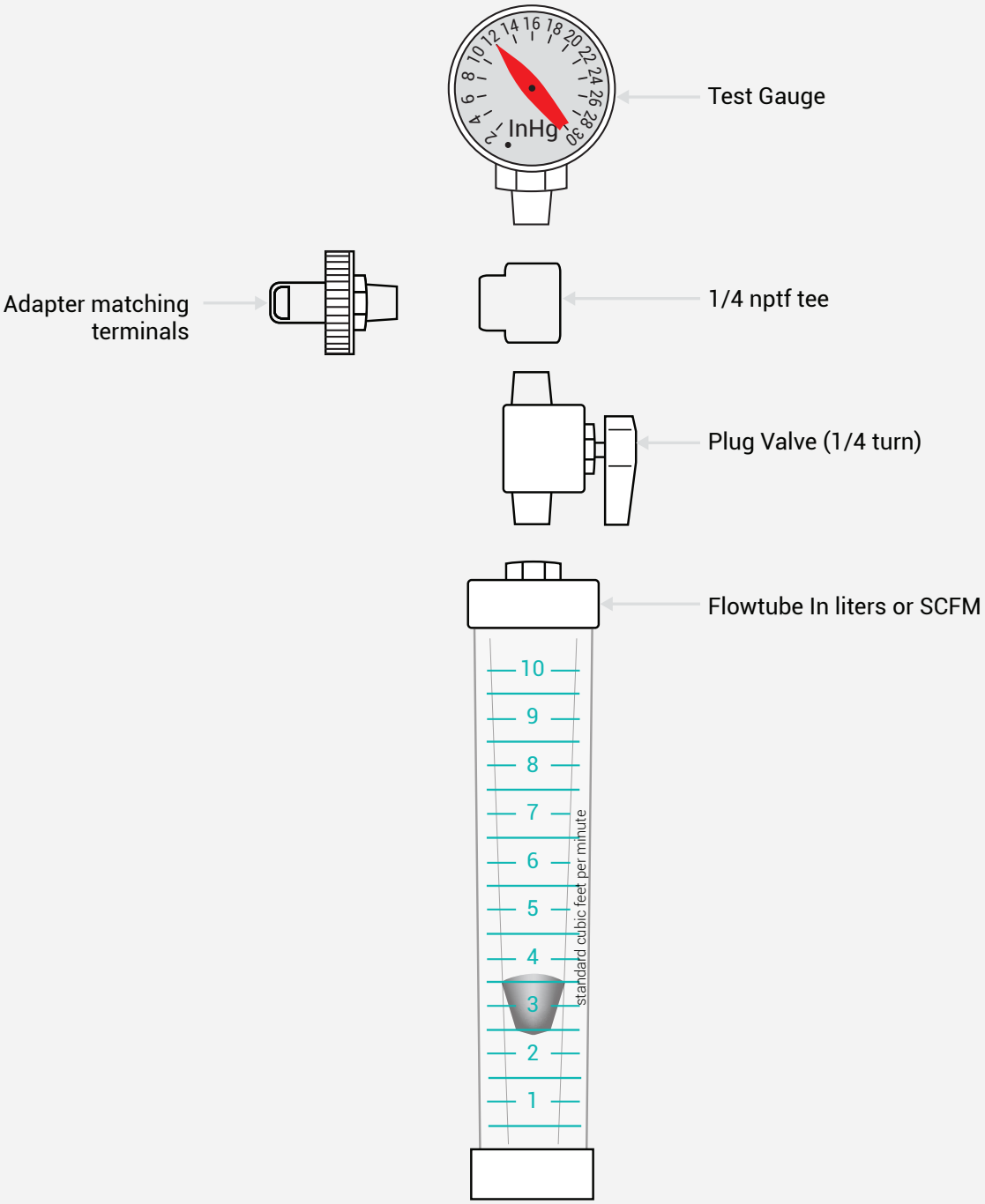
If time permits and the repair is simple, you can repair and retest.
Put only the final test on the Form, and note "Repaired" in the ***Notes*** column.

OR
note the repair needed in the Notes column and give form to maintenance planner to create a work request,

If terminals are in good condition and all pass the test, put completed Form in the medical gas terminals testing record file.

Date of tests:				**Operator**		
Terminal location room, wall and position	Lock		Static vacuum level (inHgV)	Flow at 12"Hg in scfm	Full flow in scfm	Notes
	√	X				
	√	X				
	√	X				
	√	X				
	√	X				
	√	X				
	√	X				
	√	X				
	√	X				
	√	X				
	√	X				
	√	X				
	√	X				
	√	X				
	√	X				

Flow rig assembly



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