## TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>1</td>
</tr>
<tr>
<td>Inspector Qualifications</td>
<td>7</td>
</tr>
<tr>
<td>Preparing for an On-site Inspection</td>
<td>15</td>
</tr>
<tr>
<td>Conducting an On-site Inspection</td>
<td>23</td>
</tr>
<tr>
<td>After the On-site Inspection</td>
<td>39</td>
</tr>
<tr>
<td>Additional Resources</td>
<td>43</td>
</tr>
<tr>
<td>FACT Accreditation Office</td>
<td>45</td>
</tr>
</tbody>
</table>
Thank you for volunteering your time and expertise as a Foundation for the Accreditation of Cellular Therapy (FACT) inspector! Your contributions are critical to promoting FACT’s mission of quality cellular therapy. We hope you enjoy your experiences: educating and learning from other programs or banks, networking, traveling, and advancing the field. This Inspector Handbook is intended to provide tips to inspectors in an easy-to-read guide that can accompany you on inspections.

HISTORY
Founded in 1996, FACT establishes standards for high quality medical and laboratory practice in cellular therapies. FACT is a non-profit corporation co-founded by the International Society for Cellular Therapy (ISCT) and the American Society for Blood and Marrow Transplantation (ASBMT) for the purposes of voluntary inspection and accreditation in the field of cellular therapy. The organization soon became international due to the importance of global standards for the increasing number of imported and exported products.

The major objective of FACT is to promote high quality patient care and laboratory performance in the belief that a valid accreditation must assess both clinical and laboratory aspects from donor evaluation and selection, to collection and processing, and patient administration and follow-up.
In 2000, recognizing the global impact of cord blood banking and transplantation, FACT partnered with NetCord to develop international standards for cord blood collection and banking. The NetCord Foundation is an international network of non-profit public cord blood banks created to promote the establishment of high quality cord blood banks and improve the quality of cord blood units through study and research.

In 2006, in collaboration with the Joint Accreditation Committee – ISCT & EBMT (JACIE), FACT broadened its standards in the field of cellular therapy to be international in scope. JACIE was founded by the European Group for Blood and Marrow Transplantation (EBMT) and ISCT, the two leading scientific organizations involved with cellular transplantation in Europe.

STANDARDS
FACT accredits facilities under two sets of international standards. The FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration apply to hematopoietic progenitor cells (HPC) and therapeutic cells (TC). The requirements apply to all phases of collection, processing, storage, and administration of these cells. For HPC or TC collected from umbilical cord and/or placental blood, these Standards apply only to the administration of the cord blood unit.

The NetCord-FACT International Standards for Cord Blood Collection, Processing, and Release for Administration apply to facilities and individuals performing donor recruitment and eligibility determination, cord blood collection, processing, cryopreservation, storage, testing, banking, listing, search, selection, reservation, and/or release of cord blood units. They include requirements for cord blood units intended for unrelated allogeneic, directed allogeneic, and autologous use.

These Standards were developed by international teams of experts in the field of cellular therapy and cord blood banking. The Standards contain the minimum guidelines for facilities and individuals performing cellular therapy product transplantation, cord blood banking, and/or providing support services for such activities.

ACCREDITATION
Accreditation is awarded after successful documentation of compliance with the current Standards. Compliance is determined by evaluation of written documents provided by the program or bank and by on-site inspection.

Central to all of these efforts is verification of compliance to the Standards by the FACT inspectorate. On-site inspections are carried out by a team of inspectors who are qualified by training and experience, have
completed inspector training requirements, and who have a working knowledge of the Cellular Therapy and/or Cord Blood Standards.

As a member of the FACT inspectorate, you are the face of FACT. FACT inspectors may be all that personnel at a program or bank ever sees of FACT. Conversely, FACT relies on its inspectorate to evaluate compliance with the Standards, and to represent the quality and the goals of the organization to programs that have applied for accreditation.

FACT has been fortunate to recruit excellent inspectors who have undertaken this enormous task on a voluntary basis. Without these outstanding individuals, it would have been impossible for FACT to have experienced such success with an excellent reputation.

To continue in these footsteps, this handbook is a resource to assist you with your inspection tasks. It explains some of the “dos and don’ts” of inspections. It encompasses feedback and experiences gained by FACT inspectors and from programs and banks that have been inspected. This knowledge has determined what creates an effective and positive inspection experience. This handbook passes on the guidelines and wisdom that inspectors and accredited programs and banks have developed since the inception of FACT.
All inspectors have specific educational and practical experience prerequisites to ensure they are proficient in the areas they inspect. Inspectors are active in the field of cellular therapy product transplantation, and/or cord blood banking. FACT does not use paid inspectors or FACT employees as inspectors. All FACT inspectors are volunteers who are experts with the most current knowledge of the field, and many are the researchers and innovators who are responsible for advancing cellular therapy.

**INITIAL QUALIFICATIONS**

FACT’s aim is to send out the most qualified inspectors, whose range of experience matches that of the program or bank they will inspect. To become an inspector, you were required to complete an application form detailing your professional qualifications and to be affiliated with a program or bank that was either FACT accredited or has applied for FACT accreditation.

Remember that some qualifications require maintenance over time. For example, inspectors must be a member of at least one organization from a list of identified organizations and be employed at a program that is either FACT accredited or is an active applicant for FACT accreditation. (An inspector can continue as a FACT inspector for two years after he/she leaves a FACT-accredited or applicant program.)
Please keep the FACT Accreditation Office updated on new areas of expertise, additional qualifications you have achieved, and/or any changes in your contact information (work telephone, fax numbers, email address, and mailing address) as they occur.

**INSPECTOR TRAINING and DEVELOPMENT**

FACT’s inspector training and development program is designed to ensure knowledge and understanding of current Standards, create awareness of commonly deficient and/or misinterpreted standards, and provide tools and suggestions for conducting high-quality inspections. New inspectors are required to participate in inspector training elements including the Inspection and Accreditation Workshop, the Inspector Test, and certain webinars.

**TRAINEE INSPECTORS**

After completing the application process and training requirements, you will be sent on one or more FACT on-site inspections with an experienced inspection team. You will be paired with an inspector with the same area of expertise to be your mentor and will accompany the mentor during the on-site inspection of the relevant area of the program. During that visit, you will have the opportunity to observe how an inspection is performed, how to request and review information, and interview program staff. You will also observe the pre-inspection meeting and the exit interview process.

The key thing to remember is that the trainee inspector’s role is observational. While the inspection may be a training opportunity for you, it is a very real inspection to the program or bank. Trainees are asked not to interact directly with program personnel (e.g., ask questions, share observations during the exit interview, etc.) to prevent confusion and to ensure the program’s compliance is assessed by experienced inspectors. If there are differences of opinion between a program or bank staff member and the inspector, the trainee should not become directly involved.

It is absolutely appropriate for the trainee to raise concerns or questions with his/her mentor in private and to draw attention to something that may violate a standard.

There are steps in the inspection process where you will actually do the work. While your mentor is conducting the inspection, fill out an inspection checklist and compare your findings with your mentor’s. After the inspection, work with your mentor to learn how the inspection report is prepared. You will be asked to prepare your own version of an inspection report based upon your findings and review it with your mentor to compare and
contrast findings and learn how the findings should be presented in the report.

Mentors who are accompanied by a trainee are trained to include him or her in the inspection process and to take time to explain his/her approach and findings.

CONFIDENTIALITY
Before inspectors can begin preparing for an inspection, they must complete and sign a Statement of Compliance with FACT’s Confidentiality Policy. Please remember that all information you receive or learn as part of the inspection and accreditation process is confidential. It should never be divulged or shared with others outside of the FACT Accreditation Office or inspection team. Programs undertake the inspection process on the basis that the information they provide is handled confidentially, and it is vital that they have confidence in the integrity of FACT and its representatives.

DUALITY of INTEREST
Inspectors must also complete and sign a Statement of Compliance with FACT’s Duality of Interest Policy. If you feel that you have a potentially significant duality or conflict of interest as an inspector, you must recuse yourself from the inspection. Examples of potential conflicts include a close working relationship with the program’s personnel, potential competition for referrals, and/or funding or contracts. Details of the nature of the conflict do not have to be provided to FACT. Also, bear in mind that each program or bank has the right to refuse inspectors selected by the FACT Accreditation Office for any perceived conflict of interest. The FACT Accreditation Office will make every effort to ensure potential conflicts are resolved well in advance of the scheduled date of the inspection visit. Please assist the FACT Accreditation Office by recusing yourself as soon as you determine a duality of interest exists.

ONGOING REQUIREMENTS
FACT is fortunate to have dedicated inspectors who serve its mission for several years. Due to the evolving nature of the FACT Standards and accreditation requirements, it is necessary that inspectors’ knowledge of FACT-related issues stay current. All inspectors are required to take an Inspector Test for each version of the Standards.

FACT receives feedback in a variety of ways, including on-site inspection evaluations, workshop evaluations, and written and verbal correspondence. If a trend is identified that warrants additional training, the FACT Training and Development Committee may require inspectors to participate in additional educational activities. When this is necessary, FACT ensures that the training involves minimal time and financial resources.
POLICIES and PROCEDURES
FACT has several policies and procedures that are pertinent to inspector qualifications and the inspection and accreditation process. It is FACT’s responsibility to ensure inspectors have access to SOPs, and inspectors are responsible for complying with pertinent SOPs. Policies and procedures that are pertinent to inspectors are posted on the FACT website.

INSPECTION TEAM QUALIFICATIONS
While inspectors all meet the same prerequisites for being a FACT inspector, the selection of inspection teams for specific programs and banks depends on a variety of characteristics. The services, size, and location of a program or bank impacts who is selected for an inspection team. Inspector availability for the specific dates requested by a program or bank is also a consideration.
PREPARING FOR AN ON-SITE INSPECTION

TRAVEL
FACT has limited resources, but will always try to meet your economy class travel preferences where possible. We do ask that you make airline reservations as soon as possible so that we can secure the most economical airfare. FACT works with a commercial travel agency, Travel & Transport, to assist you in making airline and hotel reservations. You may contact Travel and Transport from 8 am to 5 pm central time at 1-800-228-4395 (international travelers should call 1-402-399-2795). Travel and Transport may be contacted after hours at 1-800-237-3950 or by fax at 1-402-398-9690.

FACT asks programs and banks to provide suggestions for hotels and for travel from the airport to the hotel and from the hotel to the facility. Be sure that you have received an address and/or clear directions to your hotel and to the program or bank in case you have to travel there alone.

We recognize that you may have friends or relatives within the area of the on-site inspection and may wish to spend time with them before or after an inspection. This is permissible, but FACT will only cover your expenses directly associated with the inspection. Please ensure that you do not let personal arrangements interfere with the inspection.
You must plan on arriving in the city of the on-site inspection the **evening before** the inspection date to meet with other members of the inspection team. Departure flights must be **after 7 pm on the inspection date** to ensure a thorough inspection takes place. Your departure flight must allow for you to complete an entire day’s inspection and be present for the exit interview. This is extremely important, as inspections must not be rushed in order to catch a flight. It also shows courtesy to the program or bank personnel, who worked long and hard in the months leading up to the inspection. They take great effort to prepare for an inspection and it is neither fair to them, nor good for FACT’s reputation, to rush an inspection.

Inspectors often find it useful to stay the night after the inspection to complete their inspection report while the information is still fresh in their memory. In this situation, the extra night’s expenses are billable to FACT.

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**INSURANCE**

FACT provides insurance for its inspectors to cover any damage or accidents that may occur at a program or bank during an inspection. Details of this insurance can be obtained from the FACT Accreditation Office. In general, work-related insurance policies provided by your employer will still apply when you are performing an inspection. If in doubt, check with your employer.

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**PRE-INSPECTION REVIEW**

Once you receive the pre-inspection materials submitted by the program or bank (e.g., the Inspection Checklist and supporting documentation), you should review these carefully. Please do not wait until you get on the plane to read the information!

Your Team Leader should contact you to review inspection assignments, develop an agenda, and coordinate requests for additional information from the program or bank. Requests for documentation should be coordinated with the FACT Accreditation Office to ensure that the program or bank does not receive multiple requests for the same information. Remember, all such information is confidential.

A critical issue is the geographical layout and size of the program’s or bank’s facilities. If the program/bank is large and consists of multiple sites, you may feel that you require additional inspectors or time. This should be communicated to the Inspection Team Leader and to the FACT Accreditation Office promptly. In the case of Cord Blood Banks, it is especially important to be aware of all the Collection Sites working with the bank and if there are multiple storage facilities. If you feel you will not be able to complete your inspection in one day (cellular therapy inspections) or two days (cord blood bank inspections), you should notify the Team Leader.
and contact the FACT Accreditation Office to make arrangements for an extended stay, additional help, or a return visit as dictated by the situation.

Programs and banks are required to complete the applicant portion of the checklist and submit it to the FACT Accreditation Office prior to the on-site inspection. This completed checklist is provided to the inspector for review. When reviewing the checklist, highlight questionable items so that you are sure to address these when you visit. Examples include selection of “not applicable” on the Inspection Checklist when they are actually relevant to the inspection or the selection of “yes” despite the lack of supporting documentation.

Every program or bank is different, so be sure that you understand how the documentation is organized. Items that you may categorize as procedures may appear in their policies and vice versa. The basic structure of documentation under different quality systems (such as ISO) may be different than that of FACT, so be sure that you are careful to check that seemingly missing information is not available or presented in a different format. The FACT Accreditation Office requests copies of the Table of Contents from the SOP Manual, which is helpful to determine where to look for information.

The Standards require certain SOPs to be in place and it can be useful to request copies of the most important of these prior to the on-site inspection. Similarly, training records, competency assessments, and other documentation can be requested in advance. The more you complete ahead of time, the more efficient the on-site inspection is likely to be. It is unlikely that you will complete your inspection with time to spare.

It is a good idea to organize your paperwork ahead of the visit. The normal procedure is to follow the checklist; however, you may wish to examine certain items in more detail based upon your pre-review. It is acceptable to make a copy of your checklist and complete this, use it for notes, etc., and then transcribe the information to the original checklist.

**COMMUNICATION with the PROGRAM or BANK**

It is critical that the Team Leader contact the program or bank ahead of time to discuss the nature of the inspection, work out the provisional agenda, and review items such as the introductory presentation and the exit interview procedure. If the primary language of the program or bank is not English, work with the FACT Accreditation Office and with the program or bank to obtain translations of documents and to ensure that an adequate number of interpreters will be available at the time of the inspection.
It is also important to ensure that key personnel will be available to assist the inspectors. Arrangements should be made to visit all facilities identified as necessary by the FACT Accreditation Office. These arrangements should include transportation and escorts from the program or bank.

**PRE-INSPECTION TEAM MEETING**

All inspection teams are required to meet the night prior to the inspection or immediately prior to the inspection. The pre-inspection meeting is often the key to a well-organized and efficient inspection. Take time to cover the material in detail and review your plans. Specifically, this meeting is an important part of the process because it allows the team to:

- Review the application together and identify particular concerns or issues that may require additional attention,
- Plan the inspection itself – review the agenda and modify as necessary to ensure appropriate coverage of the entire program, and
- Allow inspectors who are sharing an area (for example, the Processing Facility) to divide the responsibility to minimize overlap, but to ensure complete coverage and adequate time to compare notes before the exit interview.

In the on-site inspection evaluation, the FACT Accreditation Office will ask you and your team members if the pre-inspection meeting took place. The joint preparation of inspection team members is critical to the success of an inspection. Sometimes, extenuating factors may prevent an in-person pre-inspection team meeting at the location of the inspection (for example, flight availability, distance between cord blood collection sites and central bank, etc.). If such factors exist, it is the responsibility of the Team Leader to plan for a meeting via teleconference. The FACT Accreditation Office will assist with arrangements if requested by the Team Leader, such as arranging for a teleconference number and/or setting up a meeting time and place.
CONDUCTING AN ON-SITE INSPECTION

BEGINNING the INSPECTION DAY
Because first impressions are so important, the inspection team must arrive at the inspection site on time and wearing business attire and your FACT Inspector identification. The Team Leader should have worked out an agenda for the inspection with the program or bank director. It is important to emphasize that time is limited and that initial presentations on both sides should be short and to the point.

The Team Leader will briefly introduce the inspectors and review the inspection process and timetable. This is followed by an overview of the program or bank by the director. The Team Leader may request that specific items be addressed in the presentation. Examples include the quality management program, how long the program/bank has been in existence and what services it provides, unique and/or outstanding characteristics of the program or bank structure, etc.

The inspection team will then divide up to conduct the particular assignments. Many inspectors like to tour the entire facility, but we strongly advise you to ensure that you leave sufficient time to perform a thorough inspection of your particular area. Every area must be seen by someone, but not necessarily by everyone.
COMPLETING the INSPECTION CHECKLIST
The inspection checklist is an important tool for inspectors. Not only does it ensure that compliance with each standard is verified, but it also provides a resource for inspectors when writing inspection reports. Furthermore, the FACT Accreditation Coordinators refer to the completed inspection checklists for clarification when needed. Therefore, complete and accurate information in the inspection checklist directly impacts the ability of the Accreditation Committee to understand the inspector’s findings during an on-site inspection. If there are ambiguities in the checklist, the FACT Accreditation Coordinator will request clarification.

The following are important reminders for completing the checklist:
• Check “Yes,” “No,” or “NA” for each question: Because the inspection checklist is the official documentation of compliance with each requirement, each question must be answered. It is not sufficient to answer only portions of the checklist, because compliance or noncompliance cannot be assumed by the FACT Accreditation Office.
• Select only one answer for each question: Programs and banks can only be in compliance with a standard if all required elements are met. If only partial compliance can be verified, check “No” and provide an explanation in the Comments field.
• Provide comments for clarity: While noncompliance with a requirement is clear for many standards (e.g., the absence of an SOP), it may not be clear for others.
• Provide notes in the Comments field: These will help you remember what the deficiencies are and provide supplemental information for the FACT Accreditation Committee. For example, if a facility is found to be inadequate for the scope of activities performed, explain why in the Comments field.

COMMUNICATING with INSPECTION TEAM MEMBERS
The inspection team conducts a working lunch meeting to privately discuss inspection findings from the morning and address particular matters of concern. If you feel that a problem must be addressed during the inspection, use the time at the lunch break to seek advice from the other inspectors or the FACT Accreditation Office. In most cases, issues focus on interpretation of a standard, and this is most easily addressed by describing the incident in your report and requesting the Accreditation Committee to make the final decision. You may also adjust your agenda if necessary.
Because cord blood bank inspections are conducted over two days, the inspection team should meet at the end of the first day. This can be done at the bank to allow you to put together a list of documentation that you would like available for the next day. Alternatively, the Team Leader may arrange with the FACT Accreditation Office for a room to be made available at your hotel for an evening meeting.

It is important that the inspection team members compare notes before the exit interview to review what will be presented to the program or bank.

The inspection team may also wish to meet after the inspection to coordinate preparation of the report.

CONDUCTING the EXIT INTERVIEW

The exit interview is intended to summarize inspection findings to the program or bank. Inspectors must use caution during this meeting, as an accreditation decision cannot be implied, nor can citations be stated with certainty that they will remain in the final inspection report. Remember that the FACT inspection and accreditation process has several layers of oversight to ensure consistency and objectivity, and changes may be made to the inspection report between the inspection and accreditation decision.

The Team Leader may choose to meet with the Program Director to apprise him/her on a one-on-one basis of the findings of the team. These private meetings are often reserved for situations in which serious deficiencies have been noted. The Program Director may then elect to hold a meeting of some or all staff to share this information. This is permissible; however, some institutions require in their policies that more than one member of the staff and/or a quality professional be present at all times during the inspection. This policy, when present, must be honored by the inspector.

Program/bank personnel attendance at the exit interview is at the discretion of the Program Director. Some may request that only key personnel be present, while some may want institutional leadership or staff-level employees to attend.

The exit interview should begin with the Team Leader thanking the program or bank for accommodating the inspection and for their time and effort. He or she should also explain what will happen after the inspection and when feedback is likely to be received. Each inspector then reviews his/her assigned area.

It is important to be constructive but realistic during the exit interview. Achieving this balance can be very difficult. Try to indicate areas where there were clear compliance or excellence. Point out major areas of
deficiency if you are certain that these are in clear violation of the Standards and that this could not be open to other interpretation. Remember that you must not indicate whether the program or bank is likely to achieve a particular accreditation outcome, or what your recommendation will be.

CONDUCT
During an inspection, personnel are generally very sensitive to an inspector’s behavior and comments. Your conduct during an inspection speaks volumes about FACT and about you.

Simple things such as politeness, a smile, and constructive suggestions can make a huge difference to the inspection process. Program and bank personnel are colleagues and the inspection process is supposed to be a collegial and helpful experience, not punitive or condescending.

It is natural that, as a professional of long standing, you will have preferences as to how to comply with a standard. Please remember, however, that not everyone feels the same way and that there are many ways to achieve compliance. As long as the method that the program or bank uses satisfies the intent of the standard, it is acceptable, even if you personally prefer a different approach. Alternative approaches may be discussed as part of the ongoing educational efforts if the personnel understand these alternatives are not required.

Differences of opinion should be expressed in a constructive manner. Do not make derogatory comments about findings or express surprise at what you find. Use the inspection checklist and report to record your concerns. If you are uncertain if a particular standard has been met, record your concerns on the inspection checklist and in your report, collect pertinent documents, and return everything to the FACT Accreditation Office. The FACT accreditation coordinators will refer any issues requiring further evaluation to the FACT Accreditation Committee and/or FACT Board of Directors.

It is appropriate to discuss your findings with personnel on an ongoing basis throughout the inspection to provide them with an opportunity to provide supplementary information or documentation. Be careful, however, that the tone of these discussions will be accurately reflected in your exit interview and final report. Personnel often complain that they had no idea of the depth and scope of deviations until they received the final report from FACT, but instead had finished the inspection feeling that they had done very well.

If you feel that there are significant problems, or that a program’s or bank’s practices are very different from the majority of others, it is appropriate to suggest alternative
approaches that may be more acceptable. Again, these suggestions should be given in a constructive manner and kept within the scope of the FACT Standards. If a staff member is not receptive to your suggestions or begins to argue about a specific point, the best policy is to move on with the inspection and note the problem on your checklist.

If a staff member of the program or bank becomes confrontational or overly aggressive, the inspector should request that another inspector accompany him or her, when possible, or have the appropriate Director identify another individual to work with the inspector. An inspector must strive to maintain his or her composure during the entire inspection. The Team Leader should address any inappropriate inspector conduct at the time it occurs. If it is not possible to remedy the situation, it should be discussed with the Team Leader and, if necessary, the inspector should remove him/herself from the inspection. If an inspector is not able to complete an inspection due to difficult program personnel, or for any reason, the FACT office should be contacted as soon as possible and the details of the issue should be included in the inspector’s evaluation of the inspection.

You should ask to see a procedure if one is ongoing, or ask personnel to mock up a procedure if an actual one is not scheduled on the inspection day. This is a routine component of the cord blood bank inspection process, particularly for collection inspections. If a real procedure is being observed, allow the personnel to work without multiple interruptions, make notes, and ask questions later. If a patient is involved, be certain the program personnel have obtained the patient’s consent to have an observer. Always be certain to follow any institutional practices of garbing, limitation to the number of persons allowed in a clean room or other area, or other issues during observation. Do not compromise patient care, or product or unit handling, by your inspection tasks.

It is desirable to praise personnel for things that are done particularly well. This can include asking them for permission to copy SOPs, labels, or other documents for your own use. The inspection is intended to be collegial and to raise quality as a whole, so this type of activity is an acceptable part of the process. Remember, though, that due to confidentiality reasons this is only permissible if you are given permission from the program or bank.

When you leave the inspection area, and at the time of the exit interview, do not indicate whether a program or bank will or will not receive a particular level of accreditation. This decision can only be made by the Accreditation Committee and the Board of Directors.
TIMING
Always remember that the program or bank has spent months of hard work preparing for the inspection process. You owe them the courtesy of performing a thorough inspection. Do not rush the process. This is where your pre-inspection preparations will pay off. It will allow you to identify areas that may require particular attention so that you can plan your time accordingly. You do yourself and FACT a disservice by appearing to rush or cut corners.

Be certain the Team Leader is aware if you feel you are running short on time. There may be another inspector on the team who can help you complete the work.

MULTIPLE INSPECTORS
Where multiple inspectors are assigned to an area, it is crucial to coordinate your efforts to ensure that there is non-repetitive, but complete, coverage and a thorough interchange of findings between the inspectors. A program or bank should never be cited for deficiencies because the inspectors failed to exchange their findings. This must occur before the exit interview so that a unified report is delivered.

Conversely, it is very frustrating for personnel to be asked to produce the same information multiple times.

Some level of cross-checking is advisable, but continual repetition is annoying.

TIPS
During the inspection, you have a lot of tools at your disposal. First impressions on entering a facility can give an indication of the level of organization and management throughout the program. Check for appropriate signage, storage conditions, tidiness, and use of protective equipment. Retrieval times for requested information can also be indicative of overall organization.

In addition to your checklist, which should remain the primary source of documentation, it may be useful to follow the progress of a product from donor screening to infusion. When questioning staff about procedures, be flexible. Allow the discussion to move into other areas, so that you can get a broader picture. It is not necessary to follow the exact order of the checklist. Determine if you hear the same information from different staff members. It is valuable to ask staff to mock up a procedure, for example, cryopreservation, to see if they follow SOPs and seem familiar with the process.

An indication of problem areas may be obtained by reviewing variances. Are there repeated occurrences of the same problem, has corrective action been taken, and
has it been effective? Remember, though, that variances and audit results are not in of themselves a reason to cite a program, but useful to assess whether or not the program or bank complies with requirements to detect and correct problems and follow up on them.

Be sensitive to the staff’s workload on the day of the inspection. Safe patient care is obviously the priority. If you feel that this is becoming a concern you should request that an individual staff member be assigned to deal with inspection issues. You can then work with him/her to coordinate the best time to tour the facility and meet with other staff if necessary.

If you see a clear deficiency that could be easily and rapidly remedied during your visit, offer the staff the opportunity to make the correction and to provide you with some form of evidence that the correction has been made. It is then not necessary to cite the program or bank for that deviation, but you should include the evidence of correction in your report. This approach cannot, however, be followed for deficiencies that are serious and would require sustained evidence of correction and implementation.

Be sure you have not overlooked something because you have searched in the wrong place. Ask the personnel to provide you with the missing documentation – they may have filed it in a different location or system.

Also remember that another SOP is not the answer to every deficiency. The Standards do require specific SOPs to be available for certain procedures, e.g., cryopreservation. In other cases, it may be possible to satisfy the intent of the standard by mechanisms other than a written SOP.

If performing an inspection in another country, be sensitive to cultural differences and language difficulties. FACT makes every effort to write Standards that do not conflict with regulatory requirements. However, if national regulations appear to be in conflict with FACT Standards, do not enter a debate but simply make a note on the checklist and in your report.

**PROGRAM COMPONENT COMMUNICATION**

A FACT requirement is that programs function as single operational units. This means that there must be evidence of interaction among all of the components. Evidence of this type of exchange is formally required in some of the standards. It is important; however, to look for such interactions when you perform the inspection of your particular area. For example, is the Collection Facility interacting and sharing information with the Clinical Program and the Processing Facility? Do the personnel know how this information is communicated and where to find it?
This type of communication is particularly important as part of the quality management program at the program or bank. Is information being exchanged efficiently so that real or developing problems can be efficiently identified and remedied? Is the program being reviewed as a whole in addition to examination of each of its component parts? Is there evidence of ongoing meetings in the form of minutes?

A comparison of notes between the members of the inspection team prior to the exit interview may also help this process.

**SUPPORTING FACT STANDARDS**

Please remember that during an inspection you are acting as a FACT representative. You may personally disagree with some of the standards; however, during an inspection you are expected to ensure that all standards are being implemented. It is inappropriate to criticize the Standards or FACT during an inspection. Such concerns should be expressed directly to the FACT Board of Directors and/or to the applicable FACT committee(s).

**MEALS and ENTERTAINMENT**

FACT allows inspection teams to receive a modest lunch provided by the program or bank and other refreshments during the inspection. Alcoholic beverages are generally not permitted during the inspection day, but may be standard in some countries.

Inspectors are discouraged from accepting other invitations of entertainment from the facility. Although such offers of hospitality are appreciated, it can be difficult and very uncomfortable for all parties to spend an evening with personnel after an inspection has raised many concerns. Expenses for other meals during the on-site visit are covered by FACT.
RESPONSIBILITIES

Once the inspection is over and you return home, the process is not complete. Please remember that what you learned is confidential and should not be discussed, even with your colleagues. If you are not clear about certain points, you should consult with other members of the inspection team, or call the program or bank for clarification.

We ask that you complete your inspection report within three days of the inspection date. This includes:

• The complete Inspection Checklist.
• The written report that clearly details for each citation the applicable Standard number and a description of the deficiency. Also include a list of missing documents, suggestions for improvement, and any additional comments or recommendations that you feel may help the FACT Accreditation Committee in evaluating the program’s or bank’s compliance.
• Additional documentation obtained during the on-site inspection to support your observations (for example, clinical facility data sheets, updated forms, etc.).

Make two copies of all of the documents obtained during the inspection, completed checklists, and notes.
taken that are associated with the inspection. Keep one copy for yourself, send another copy to the Team Leader, and send the originals to the FACT office. Both electronic and hard copies should be submitted, if available. (Note: After you have been notified that the program or bank has received FACT accreditation, all materials related to the inspection must be destroyed.)

The Team Leader should compile all the inspector reports into a single report and submit all necessary documents to the FACT Accreditation Office.

A prompt report is the easiest to prepare, and it makes a huge difference to the inspection turnaround time. It allows the FACT accreditation personnel to prepare a summary report for the FACT Accreditation Committee, and for the Committee to review this information and make the accreditation decision in a timely manner. Since the Accreditation Committee meets on a monthly basis, a delay in submitting your report could mean that the decision would be deferred to a later Committee meeting. This is particularly true for cord blood inspections where reports are reviewed by the Board of Directors of both FACT and NetCord.

As an “encouragement” to meeting FACT timelines, you will not receive your reimbursement until your inspection report has been received.

**PERFORMANCE**

FACT asks the program or bank, the inspectors, and FACT personnel to complete an evaluation report on the inspection process after each inspection visit. This helps FACT identify problem areas in the Standards, the inspection process, and inspector conduct. Inspection feedback will also be incorporated into future inspector training sessions. Please take a moment to complete the evaluation form that you are sent electronically and return it with your inspection report and expenses to the FACT Accreditation Office.

FACT reviews the evaluations on an ongoing basis with its committees. When necessary, the committees will investigate specific complaints from programs, banks, inspectors, and FACT staff.
The FACT Accreditation Office and the FACT committees continuously update resources for FACT inspectors to assist them with inspections. An Inspector Area is designated on the FACT website, through which inspectors can access training sessions, guidelines, and other tools free of charge.

Ongoing communication regarding interpretation of specific standards, educational opportunities, accreditation activities, and information from FACT’s parent organizations is provided via the online quarterly newsletter, *Just the FACTs*, and email announcements. All inspectors are added to this email distribution list. If you do not receive the newsletters or email announcements, please contact the FACT office.
The FACT Accreditation Office is pleased to help you with general comments, questions, or concerns.

GENERAL INFORMATION

Hours: 8 am to 4:30 pm central time

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