

CAR 521 Regulatory Initiative

Risk Assessment Report and Recommendations

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EXECUTIVE SUMMARY

This document is the product of a Risk Assessment (RA) conducted on the CAR 521 regulatory initiative. The RA was conducted in accordance with the terms of reference presented at CARC on 26th May 2004. Mr. Cameron Fraser from RANA International acted as Process Consultant and Facilitator and prepared the final report using the information produced by the RA team composed of representatives from both the Aircraft Certification and Aircraft Maintenance and Manufacturing Branches.

In accordance with the "CARAC Procedure for initiating RA on Regulatory Proposals" as specified in CARC Decision Record dated 25th March 2004, item No. 04/03/25-12.2, the scope of this RA was focused on those elements which are not harmonizing with the FAA and ICAO and those not of an administrative nature. Over forty items were identified as components of the hazards and grouped based on commonalities in seven categories as follows:

- (1) Replacement of Limited Supplemental Type Certificate (LSTC) by serialized STC;
- (2) Definition of a standard for Flight Test Operations;
- (3) Replacement of the existing Appliance Type Certificate by Technical Standard Order Design Approval (TSO DA);
- (4) Applicant's obligation to submit a statement of compliance with obligations;
- (5) Upon surrender of a Certificate or Approval, obligations of the holder to surrender data to the Minister;
- (6) Conformity Inspections of test articles; and,
- (7) Applicant's obligations to declare compliance to the certification basis.

A number of unique components were also identified. All components were prioritized in terms of their probability and severity. Risk scenarios were developed and evaluated for those categories of highest probability and severity.

The level of risks associated with the holder's obligations to surrender data to the Minister upon surrender of a Certificate or Approval (item # 5 above) was considered unacceptable and it was decided to remove this provision from the proposed regulation.

A number of risk scenarios associated with Compliance with obligations (item # 4 above) were identified as having highest risk index. The consequences of these risks scenarios included embarrassment to the Minister and applicants not being able to fulfill their continuing airworthiness obligations. These risks scenarios were predominantly resulting from potential misunderstanding of the regulations by both TCCA personnel and applicants. The resulting risk control measures consist of extensive guidance material and associated training program considered essential to ensure optimum knowledge and understanding of all CAR 521 elements. A detailed set of action plan activities was defined to implement the control measures. This action plan will rely heavily on lessons learned from previous regulatory initiatives including SMS, CPR and PDA.

In summary, the overall risk associated with the CAR 521 regulatory initiative was considered low to medium and manageable except for potential misunderstanding of the regulation that requires implementation of the following risk control option:

CAR 521 will require the development of guidance, training, and publicity material in parallel, using current approaches, testing both with the prototype training so that refined materials and training are available at time of Gazette publication.

Document Outline

This document is the product of a Risk Assessment conducted on the CAR 521 Regulatory Initiative. RANA International, who acted as Process Consultants and Facilitators, prepared it using the information produced by the Transport Canada Risk Assessment Team. Items preceded by the term **Process Notes** are comments from the consulting company to provide information on the Risk Management methodology, including variations/deviations from the Type 2A process in order to customize its application to this case.

In addition to the Summary Report found on the previous page the Risk Assessment report is comprised of four sections. These are:

- The Type 2A Risk Management worksheets
- Appendix 1: The Terms of Reference for the assessment
- Appendix 2: Initial Sort – A table outlining CAR 521 and identifying those elements of CAR 521 that were subject to the Risk Assessment according to the terms of reference. In addition, information is provided linking like items together as a way of reducing the total number of assessments required and/or eliminating repetitive assessments (See step 2)
- Appendix 3: A record of team deliberations and discussions which provides background and rationale on decisions made

STEP 1: INITIATE THE PROCESS

S1.1 Describe the situation/activity

Outline basic situation/activity

Transport Canada intends to improve the regulations governing aircraft certification and align them with FAR 21 and the European IR-21. While much of this work will be an administrative change collecting information from a number of separate documents (CAR 511, AWM 511, CAR 513, AWM 513, CAR 516, CAR/AWM 537, CAR/AWM 591 and CAR/AWM 593), this will create some elements which are completely new.

Associated Issues

- SMS: The inclusion of SMS in CAR 521 may be a contentious issue because of it being a relative unknown. This is both internal to Transport Canada Civil Aviation and external (industry).

Assumptions

- Adequate understanding of the risks associated with the portions of CAR 521, which are extracted from the existing CARs, and/or are harmonized with FARs, exists and no risk assessment is required for those.

Constraints

- The scope of the risk assessment is limited to those elements which are:
 - Derived strictly from European IR's;
 - Completely new (not derived from an existing Canadian document), and/or;
 - Not harmonized with FAR's
- Time – In order to have the information from the risk assessment available for scheduled uses the work must be complete by 06 August 2004
- The size and makeup of the team. The team is relatively small and includes individuals close to, and with a stake in the success of, the CAR 521 project

S1.2 What is the hazard?

The creation of portions of CAR 521 which are completely new and/or not harmonized with FAA and/or International Civil Aviation Organization (ICAO).

S1.3 Identify the risk assessment team

<i>Key Competencies Needed</i>	<i>Possible Team Member</i>	<i>What is the authority of that person in the RM group?</i>
Facilitator/ Knowledgeable of RM Type 2A	Cameron Fraser, RANA International	Process Only
Knowledge of compatibility with Maintenance & Manufacturing Regulation to be incorporated in CAR 521 in the future	Bill Fossey	Content Only
<p>Knowledge of the certification process.</p> <p>Knowledge and understanding of foreign Certification process (US and Europe)</p> <p>Knowledge of bi-lateral airworthiness agreements</p>	Gilles Morin	Content only
<p>Knowledge of the certification process.</p> <p>Knowledge and understanding of foreign Certification process (US and Europe)</p> <p>Knowledge of bi-lateral airworthiness agreements</p>	Crystal Cartney	Content only
<p>Knowledge of the certification process.</p> <p>Knowledge and understanding of foreign Certification process (US and Europe)</p> <p>Knowledge of bi-lateral airworthiness agreements</p>	Martin Thieringer	Decision on final recommendations

<p>Knowledge of consistency with 505 and guidance material developed - Delegation</p>	<p>Due to schedule conflicts Delegation was unable to provide a team member on an ongoing basis. Delegation did participate in pre RM consultations. Derek Ferguson was available as required to deal with specific issues.</p>	<p>Content contribution only</p>
<p>Aircraft certification regulatory expertise - Projects</p>	<p>Allen Lyon</p>	<p>Content Contribution only</p>
<p>Aircraft Certification Flight Test</p>	<p>Jim Thomson</p>	<p>Content and risk scenarios for Flight Test only</p>
<p>Commercial and Business Aviation</p>	<p>NOTE: C&BA declined participation, as they believed there was no impact on their operations. No obligations or burdens have changed.</p>	

S1.4, S1.5 & S1.6 Who are the stakeholders, Is Consultation Necessary, and Is the stakeholder consultation within the team's scope?

Stakeholder	Is consultation necessary?	Method of contact	Who is responsible?	When will the consultation occur?
Internal	No			
External	No			
Public	No			

Note: Extensive consultation, internal and external has taken place in preparation of the CAR 521 document. The team has the expertise and both the required technical knowledge, and knowledge of stakeholder points of view, to conduct a realistic and appropriate risk assessment.

STEP 2: PRELIMINARY ANALYSIS & ESTIMATING THE RISK

Process Note:

As per the terms of Reference, the scope of the risk assessment is limited to those elements which are:

- Derived strictly from European IR's;
- Completely new (not derived from an existing Canadian document), and/or;
- Not harmonized with FAR's

Therefore the components of the hazard were identified as those elements of CAR 521 that fit the description in the ToR.

In order to manage the constraint of time the process of identifying Components of the Hazard and Associated Risks was modified at the suggestion of RANA International. The process used was iterative and intended to reduce the quantity of components of the hazard that needed to be analyzed:

1. Identify and list those regulations in CAR 521 which:
 - Are derived strictly from European IR's;
 - Are completely new (not derived from an existing Canadian document), and/or;
 - Are not harmonized with FAR's
2. Identify any commonalities or links between the regulations in the list resulting from step 1, grouping common items together for the purposes of risk assessment.
3. For those items with links providing a brief text description to ensure a common understanding of the primary concern with the category.

The second step resulted in the identification of several areas of concern, which encompassed a number of regulations within CAR 521, and a number of unique regulations. These are listed in the following chart. This grouping of items with commonalities allowed an initial list of forty items to be reduced to seven categories and five unique items, which proved more manageable within the time constraint.

In a further effort to ensure the team was able to deal with the most critical issues within the time constraints two steps of initial prioritization were undertaken. These were:

1. After the initial identification of the Components of the Hazard to assess their relative importance on an A-1 Essential, A Important, B of interest, C relatively unimportant (relative to the other categories/regulations), scale.
 - In order to identify priorities the team considered the following criteria:
 - Imparts a significant change to the current regulations.
 - Introduces or removes a burden on the applicant/holder.
 - Introduces or removes a burden on the Minister.
 - Changes costs to the applicant/holder.
 - Changes the efficiency of the certification process.
 - Provides a net benefit to the applicant/holder.
 - Improves Minister's ability to fulfill responsibility re: Aeronautic Act.

- Involves international recognition.
2. After initial identification of Associated Risks (beginning with the highest priority areas identified in the previous step) to assess the risks in terms of probability and severity on a High, Medium, Low scale.

It is important to note that while this prioritization is not normally a part of a type 2A process, it is consistent with the Type 2 approach from which the Type 2A was derived, and that the technique was adopted strictly in response to the time constraints.

If viewing the following chart electronically, the following colour coding is relevant:

- Under the Probability and Severity columns:
 - Green indicates low
 - Yellow indicates Medium
 - Red indicates High
- Under the Associated Risk Column
 - Green indicates low concern as a result of low probability and severity
 - Yellow indicates medium concern as a result of some higher combination of probability and severity (i.e. Low & High, Medium and Medium)
 - Red indicates high as a result of High probability and High severity

S2.1 What are the components of the hazard and associated risks?

Components of the hazard	Priority	Associated Risks	Initial Assessment	
			Prob	Sev
<p>LSTC to serialized STC</p> <p>This is primarily about...</p> <p>Removing LSTC (generally a single fleet) and moving to STCs limited to a serial number range and removes other restrictions.</p> <ul style="list-style-type: none"> Serial STC at the same data level and all obligations remain LSTC has a lower data level LSTC is not internationally recognized 	<p>A-1 Essential</p>	<p>There may be resistance from industry due to cost increase associated with higher data level.</p>	Low	Low
		<p>There may be an increased workload for TCCA because the higher standard for data packages will require more extensive review.</p>	Low	Med
		<p>Someone reading the CAR may not understand options on STC varieties; elimination of the term LSTC will be confused by industry.</p>	Low	Low
<p>Flight Test Operations</p> <p>This is primarily about...</p> <p>Putting in a standard for manufacturers that have a flight Test Operation and setting standards for that operation</p> <ul style="list-style-type: none"> Large OEMs 	<p>A-1 Essential</p>	<p>Industry may not be able to support this with sufficient flight test resources.</p>	Low	Low
		<p>Applicability of requirement to large OEMs may be misunderstood.</p>	Med	Low
		<p>Flight test operations are a novel requirement in aircraft certification. It is not in FAR, or IR 21, and it is not harmonized. This may be an unfair burden or inadequately addressing a problem as a result of the novel requirement.</p> <p>Note; This associated risk was initially assessed as High/High due to lack of information but was reduced to Low/Low following clarification from Jim Thompson (AARDC) on the rationale for this unique Canadian requirement.</p>	Low	Low

S2.1 What are the components of the hazard and associated risks?

Components of the hazard	Priority	Associated Risks	Initial Assessment	
			Prob	Sev
		Credibility of TC for lack of standard.	Low	Med
		Increased workload to TCCA.	High	Low
		Flight test now involved in approval of operations manual, and there may be inconsistent approval of the ops manual because there may not be a standard.	Low	Med
Division O This is primarily about... The replacement of an appliance type certificate with TSO DA.	A-1 Essential	Unique Canadian TSO may not be recognized internationally.	High	High
		Unique Canadian TSO-DA may not be recognized internationally.	Med	High
		There may be a different level of involvement by TCCA versus FAA in the issue or acceptance of a TSO-DA. This may result in the perception of an unequal playing field.	High	Low
		There may be an inconsistent application of C-TSO-DA by TCCA and industry personnel.	Med	Med

S2.1 What are the components of the hazard and associated risks?

Components of the hazard	Priority	Associated Risks	Initial Assessment	
			Prob	Sev
<p>Compliance with Obligations</p> <p>This is primarily about...</p> <p>The applicant's written statement that they will comply with the obligations and responsibilities to maintain the continued airworthiness of the product (SDR, AD, SMS)</p>	<p>A-1 Essential</p>	<p>Demonstrating a technical capability to show compliance is quite different than having a technical capability to put SMS in place. They may have technical capability but not an understanding of how to apply an AD. The entire safety culture of SMS and integrated reporting systems etc. does not necessarily include an understanding of how to do something. The potential Type certificate holder at the start of the process may not understand the obligation. Eligibility talks about technical capability, not management capability.</p>	High	Med
		<p>The applicant may refuse to comply.</p>	Low	Low
		<p>The applicant may not fulfill continuing airworthiness responsibilities.</p>	Low	High
<p>Duration</p> <p>This is primarily about...</p> <p>The obligations of a holder of a certificate upon releasing a certificate to the Minister, and surrendering the data so that the Minister may maintain the continued airworthiness of the product.</p>	<p>A-1 Essential</p>	<p>The Minister may not have sufficient resources or clear procedures to fulfill this responsibility.</p>	Med	Med
		<p>There is no financial or legal consideration regarding the transfer of a certificate from the Minister, to whom it was surrendered, to a new holder. This would be a conflict of interest situation.</p>	Low	High
		<p>There may be situations where the STC information is not available for surrender to the Minister (assuming Minister is the holder).</p>	Med	High

S2.1 What are the components of the hazard and associated risks?				
Components of the hazard	Priority	Associated Risks	Initial Assessment	
			Prob	Sev
		Although the owner may surrender the property rights, he may not surrender all the data—and the Minister therefore may not be able to meet his obligations for continuing airworthiness.	High	High
		Continuing airworthiness of the product may be in doubt.	Low	High
		The Minister may not be able to fulfill his ATIP responsibilities if the data is not surrendered.	Low	High
<p>Conformity This is primarily about...</p> <p>Ensuring that the test specimen conforms to the proposed type design by performing an engineering conformity and ensures that all equipment is properly calibrated to perform the tests. There is a need for the test specimen to be identified to the Minister for access and witnessing of the test.</p>	A-1 Essential	There may be an unclear distinction between engineering conformity and product conformity (AM&M). There may be an overlap of responsibilities.	Med	Low
		Calibration standards not specified.	Low	Low
		The equipment may be inappropriate, or improperly calibrated.	Low	Low
		There is a risk that the Minister will get involved in disputes between companies over access to intellectual property.	Low	High
		There may not be personnel available to witness the test.	Med	Low

S2.1 What are the components of the hazard and associated risks?

Components of the hazard	Priority	Associated Risks	Initial Assessment	
			Prob	Sev
<p>Declaration</p> <p>This is primarily about...</p> <p>Specifying the responsibility of an applicant to make a statement that they have shown compliance to the applicable certification basis</p>	<p>A</p> <p>Important</p>	The applicant may refuse to comply.	Low	Low
		The applicant may edit or transfer the statement in cases of Flight Test, because in that situation, the Minister may be taking on the partial role of the applicant. Minister may have to assume some liability for showing compliance for the Flight Test portion.	Med	High
		The applicant may make a false statement of compliance.	Low	High

Process Note:

The following categories / regulations were identified as B and C Priorities in the initial sorting mentioned earlier in the report. While the time spent on examining this was very short due to time constraints the team was unable to identify any significant Associated Risks. The belief of the team was that the risks associated with B and C Priority items are so relatively low as to not require assessment.

S2.1 What are the components of the hazard and associated risks?				
Components of the hazard	Priority	Associated Risks	Initial Assessment	
			Prob	Sev
<p>RDA Applicability to a TSO item (roadmap)</p> <p>This is primarily about a roadmap pointing the applicant to the appropriate certification process:</p> <p>Holder complies with Division O; and</p> <p>Non-holder complies with Division M.</p>	B	None Identified	Refer to Process Note above	
<p>Continuation of ODA</p> <p>This is the obligation that every three years from their anniversary date the ODA holder request continuation of their authorization. It exists to provide the minister a basis to remove delegation if the individuals cannot be found</p>	B	None Identified		
<p>Classification of Change</p> <p>This is primarily about determining the procedures to be used when making a major or minor modification to a type design</p>	B	None Identified		
<p>Part Marking</p> <p>This is primarily about a roadmap pointing the holder of an approval or certificate to CAR Part II on how to mark a part</p>	C	None Identified		

S2.1 What are the components of the hazard and associated risks?

Components of the hazard	Priority	Associated Risks	Initial Assessment	
			Prob	Sev
<p>Clarification Statement Roadmap...What your responsibility is depending on who you are.</p>	C	None Identified		

Process Note:

Prior to developing Risk Scenarios based on the Associated Risks developed in Step 2.1, the team identified the Exposure interval (that time over which the risks should be considered) as 10 years. This period was chosen as reflecting the likely time frame between the promulgation of CAR 521 and a major review of that regulation.

The team developed Risk Scenarios in order of priority rather than working through all risks associated with a particular component of the hazard. This ensured that the major concerns would be dealt with first and within the time constraints. The sequence in which scenarios were developed for Associated Risks was determined by:

- The priority of the area (A-1, A, B, C), and then by;
- The initial assessment of Probability and Severity (High, Medium and Low)

As a result of time constraints no scenarios were developed for the following areas:

- LSTC to Serialized STC
- Conformity

The team did take a short time to reflect on these areas and determined that in the case of LSTC to Serialized STC the initial assessment of probability and severity indicated little concern about this area. The area of Conformity was assessed similarly with the one case (i.e. The risk that the Minister will get involved in disputes between companies over access to intellectual property) with potentially higher severity having such low probability of occurring as not to be worth pursuing.

In the following Risk Scenario and Assessment chart the following colour coding applies:

- Green – Level 0 or 1 Risk
- Yellow – Level 2 Risk
- Red - Level 3 Risk

It should be noted that the Terms of Reference required the risk assessment of anything that was assessed at level 2 or higher according to the scale and description of risk assessment in the type 2A process.

S2.2 What is the exposure interval?		10 Years				
S2.3 Develop risk scenarios Flight Test Operations		S2.4 Establish consequences	S2.5 Assess Probability, Severity & Exposure (provide explanations as necessary)			
Sequence of Events	Cause (N, E, T, H)	Consequences	Probability	Severity	Exposure	Risk level
Risk Scenario #1						
1. Addressed informally/accident changed that 2. No requirement 3. Operator doesn't have manual 4. Operators asking for guidance/seek expertise 5. Increase TC workload for TC Flight Test	Technical	Impact or delays on other activity within Flight Test	1	1	1	1
		Delays in approval of manuals because of the other activities in flight test	1	1	1	1
		Reduction in time available to assist regions	1	1	1	1
		Smaller OEMs will require the most effort	2	1	1	2
Risk Scenario #2						
1. New requirement/ no resources or experts to write manual 2. Applicant not sure if documentation is sufficient 3. Operator doesn't have manual 4. Operators asking for guidance/seek expertise 5. Increase TC workload for TC Flight Test	Technical	Impact of delays on other activity within Flight Test	1	1	1	1
		Delays in approval of manuals because of the other activities in Flight Test	1	1	1	1
		Reduction in time available to assist regions	1	1	1	1
		Smaller OEMs will require the most effort.	2	1	1	2

S2.2 What is the exposure interval?		10 Years				
S2.3 Develop risk scenarios Division O		S2.4 Establish consequences	S2.5 Assess Probability, Severity & Exposure (provide explanations as necessary)			
Sequence of Events	Cause (N, E, T, H)	Consequences	Probability	Severity	Exposure	Risk level
Risk Scenario #1						
1. New Canadian vehicle replacing Special Conditions Airworthiness when no standards exist. 2. No legal framework to consult on Canadian TSO 3. Canadian TSOs are not consulted publicly 4. Unique Canadian TSO not recognized internationally [H/H] 5. Unique Canadian TSO-DA not recognized internationally	Technical	Resources spent for a standard that will still not be recognized internationally.	3	1	2	6
		Labour to market to the FAA if the C-TSO is based on a recognized international standard (i.e. SAE)	1	2	2	4
		Foreign marketability of product; may result in higher workload to Minister for an STC	2	1	2	4
		Aircraft orphans; aircraft cannot be exported and buyers in other countries cannot purchase Canadian aircraft.	1	0	---	0
Notes						
It's really a legal technical issue, rather than a mechanical technical issue. These are not economic issues.						
Risk Scenario #2						
1. Novel product/novel requirement 2. No foreign TSO to adopt 3. Using a different approval vehicle for these products 4. Unique Canadian TSO not recognized internationally [H/H] 5. Unique Canadian TSO-DA not recognized internationally	Technical	Resources spent for a standard that will still not be recognized internationally.	3	1	2	6
		Labour to market to the FAA if the C-TSO is based on a recognized international standard (i.e. SAE)	1	2	2	4
		Foreign marketability of product; may result in higher workload to Minister for an STC	2	1	2	4
		Aircraft orphans; aircraft cannot be exported and buyers in other countries cannot purchase Canadian aircraft.	1	0	---	0

S2.2 What is the exposure interval?		10 Years				
S2.3 Develop risk scenarios Division O		S2.4 Establish consequences	S2.5 Assess Probability, Severity & Exposure (provide explanations as necessary)			
Sequence of Events	Cause (N, E, T, H)	Consequences	Probability	Severity	Exposure	Risk level
Risk Scenario #3						
1. Novel product/Novel requirement 2. No foreign TSO to adopt 3. Foreign Regulatory Barriers/Bilateral agreements not addressed 4. Unique Canadian TSO not recognized internationally [H/H] 5. Unique Canadian TSO-DA not recognized internationally	Technical	Resources spent for a standard that will still not be recognized internationally.	2	1	2	4
		Labour to market to the FAA if the C-TSO is based on a recognized international standard (i.e. SAE)	1	1	2	2
		Foreign marketability of product; may result in higher workload to Minister for an STC	1	1	2	2
		Aircraft orphans; aircraft cannot be export and buyers in other countries cannot purchase Canadian aircraft.	1	0	---	0

S2.2 What is the exposure interval?		10 Years				
S2.3 Develop risk scenarios Compliance with obligations		S2.4 Establish consequences		S2.5 Assess Probability, Severity & Exposure (provide explanations as necessary)		
Sequence of Events	Cause (N, E, T, H)	Consequences	Probability	Severity	Exposure	Risk level
Risk Scenario #1						
1. Totally new to the business 2. Did not have the technical ability or understanding 3. Applicant didn't understand the regulations 4. The obligations may not be understood by the potential Type Certificate holder at the start of the process	Human	Continuing Airworthiness responsibilities not fulfilled	Refer to Notes below			
		Aircraft Accident				
		Grounding of the fleet				
		Inconsistent application of 521				
		Lawsuits				
		Embarrassment to the Minister				
		Withdrawal/suspension of approval of type certificate				
Notes						
Scenario one was removed on the grounds that it was not a plausible scenario. An applicant totally new to the aircraft business would be strongly encouraged to proceed through a delegate. Consequently, scenario #2 below has been revised to include that step where an agent or delegate would be involved.						
Risk Scenario #2						
1. Totally new to the business 2. Potential type certificate holder used an agent on his behalf 3. Applicant did not have technical ability or understanding 4. Applicant didn't understand the regulations 5. The obligations may not be understood by the potential Type Certificate holder at the start of the process	Human	Continuing Airworthiness responsibilities not fulfilled	4	1	1	4
		Aircraft Accident	2	3	1	6
		Grounding of the fleet	2	1	1	2
		Inconsistent application of 521 by Industry	2	1	1	2
		Lawsuits	1	2	1	2
		Embarrassment to the Minister	1	3	1	3
		Withdrawal/suspension of approval of type certificate	1	1	1	1

S2.2 What is the exposure interval?		10 Years				
S2.3 Develop risk scenarios Compliance with obligations		S2.4 Establish consequences	S2.5 Assess Probability, Severity & Exposure (provide explanations as necessary)			
Sequence of Events	Cause (N, E, T, H)	Consequences	Probability	Severity	Exposure	Risk level
Risk Scenario #3						
1. Applicant hasn't done homework, hasn't read the CARS or guidance material 2. Applicant didn't understand the regulations 3. The obligations may not be understood by the potential Type Certificate holder at the start of the process	Human	Continuing Airworthiness responsibilities not fulfilled	4	1	1	4
		Aircraft Accident	2	3	1	6
		Grounding of the fleet	2	1	1	2
		Inconsistent application of 521 by Industry	2	1	1	2
		Lawsuits	1	2	1	2
		Embarrassment to the Minister	1	3	1	3
		Withdrawal/suspension of approval of type certificate	1	1	1	1
Risk Scenario #4						
1. TCCA underestimated scope of the project 2. Lack of resources (human or time) in TCCA 3. TCCA did not have appropriate guidance material 4. TCCA interface doesn't understand changes 5. Applicant didn't understand regulations 6. The obligations may not be understood by the potential Type Certificate holder at the start of the process	Human	Continuing Airworthiness responsibilities not fulfilled	2	2	2	8
		Aircraft Accident	1	3	2	6
		Grounding of the fleet	1	1	2	2
		Inconsistent application of 521 by TC	2	1	2	4
		Lawsuits	2	2	2	8
		Embarrassment to the Minister	2	3	2	12
		Withdrawal/suspension of approval of type certificate	1	1	2	2

S2.2 What is the exposure interval?		10 Years				
S2.3 Develop risk scenarios Compliance with Obligations		S2.4 Establish consequences	S2.5 Assess Probability, Severity & Exposure (provide explanations as necessary)			
Sequence of Events	Cause (N, E, T, H)	Consequences	Probability	Severity	Exposure	Risk level
Risk Scenario #5						
1. TCCA underestimated scope of the project 2. Lack of resources (human or time) in TCCA 3. Inadequate CAR 521 Training Program 4. TCCA interfaces doesn't understand changes 5. Applicant didn't understand regulations 6. The obligations may not be understood by the potential Type Certificate holder at the start of the process	Human	Continuing Airworthiness responsibilities not fulfilled	2	2	1	4
		Aircraft Accident	1	3	1	3
		Grounding of the fleet	1	1	1	1
		Inconsistent application of 521 by TC	1	1	1	1
		Lawsuits	2	2	1	4
		Embarrassment to the Minister	2	3	1	6
		Withdrawal/suspension of approval of type certificate	1	1	1	1
Risk Scenario #6						
1. TCCA underestimated scope of project 2. Lack of resources (human or time) in TCCA 3. TCCA did not have appropriate Guidance material 4. The applicant didn't understand the regulations 5. The obligations may not be understood by the potential TC holder at the start of the process	Human	Continuing Airworthiness responsibilities not fulfilled	3	2	2	12
		Aircraft Accident	1	3	2	6
		Grounding of the fleet	1	1	2	2
		Inconsistent application of 521 by TC	3	1	2	6
		Lawsuits	2	2	2	8
		Embarrassment to the Minister	2	2	2	8
		Withdrawal/suspension of approval of type certificate	1	1	2	2

S2.2 What is the exposure interval?		10 Years				
S2.3 Develop risk scenarios Compliance with Obligations		S2.4 Establish consequences	S2.5 Assess Probability, Severity & Exposure (provide explanations as necessary)			
Sequence of Events	Cause (N, E, T, H)	Consequences	Probability	Severity	Exposure	Risk level
Risk Scenario #7						
1. TCCA underestimated scope of project 2. Lack of resources (human or time) in TCCA 3. TCCA had inadequate CAR 521 training program 4. Applicant didn't understand the regulations 5. The obligations may not be understood by the potential TC holder at the start of the process	Human	Continuing Airworthiness responsibilities not fulfilled	2	2	1	4
		Aircraft Accident	1	3	1	3
		Grounding of the fleet	1	1	1	1
		Inconsistent application of 521 by TC	2	1	1	2
		Lawsuits	1	2	1	2
		Embarrassment to the Minister	1	2	1	2
		Withdrawal/suspension of approval of type certificate	1	1	1	1

S2.2 What is the exposure interval?		10 Years				
S2.3 Develop risk scenarios		S2.4 Establish consequences		S2.5 Assess Probability, Severity & Exposure (provide explanations as necessary)		
Duration						
Sequence of Events	Cause (N, E, T, H)	Consequences	Probability	Severity	Exposure	Risk level
Risk Scenario #1						
<ol style="list-style-type: none"> 1. Holder did not understand regulatory requirements 2. Holder does not have appropriate record keeping 3. Type Certificate surrendered with incomplete data 4. TCCA doesn't know if they have complete information 5. Data submitted or available for ongoing airworthiness may be limited [H/H] 	Human	The Minister becomes a holder, and has to fulfill the responsibilities of being a holder, while at the same time, having to regulate himself.				
		Orphaned equipment, parts, appliances and aircraft				
		The Minister may not be able to fulfil the Access to Information and Privacy Act responsibilities				
		Minister is perceived to be going into business if he is approached to sell Type Design data that he holds, to restart production				
		Minister cannot fulfil his responsibilities of 4.2(n) of the Aeronautics Act, which was the intent of including this provision				
		Inconsistency with previous Transport Canada Ministers' position of not providing services that industry should be providing				
		The Minister would have difficulty regulating the purchaser, having sold the data to him.				
		Conflict with Delegation of Authority				
		Liability concerns—Minister may have sold incomplete data without knowing it				
		Type certificates might have to be sold by tender				

Refer to Notes below

S2.2 What is the exposure interval?		10 Years				
S2.3 Develop risk scenarios		S2.4 Establish consequences		S2.5 Assess Probability, Severity & Exposure (provide explanations as necessary)		
Duration						
Sequence of Events	Cause (N, E, T, H)	Consequences	Probability	Severity	Exposure	Risk level
Notes						
<p>Having identified the scenarios and consequences, the team determined the following:</p> <ol style="list-style-type: none"> 1. The obligations of the Minister would be difficult to fulfill 2. This exposes the Minister to high risk, while regulating a small percentage of clients 3. The regulation is unlikely to be approved by Justice because of the proprietary information clause 4. The Minister is perceived to be going into business <p>This particular piece of CAR 521 generates many significant consequences, while addressing a very small concern. The estimated impact would be significant. The team determined that the risk was unacceptable, and chose to remove from the regulation the provision requiring the holder to surrender its proprietary data to the Minister while retaining the provision specifying the duration of certificate/approval.</p>						
Risk Scenario #2						
<ol style="list-style-type: none"> 1. Type Certificate holder retains proprietary data and submits incomplete data 2. Type Certificate surrendered with incomplete data 3. TCCA doesn't know if they have complete information 4. Data submitted or available for ongoing airworthiness may be limited 	Human	Refer to Notes to Scenario #1 above.				
Risk Scenario #3						
<ol style="list-style-type: none"> 1. Type Certificate holder purchased certificate without data, or the data was not transferred 2. Surrendered to TCCA with no data 3. Data submitted or available for ongoing airworthiness may be limited 	Human	Refer to Notes to Scenario #1 above.				

S2.2 What is the exposure interval?		10 Years				
S2.3 Develop risk scenarios Duration		S2.4 Establish consequences	S2.5 Assess Probability, Severity & Exposure (provide explanations as necessary)			
Sequence of Events	Cause (N, E, T, H)	Consequences	Probability	Severity	Exposure	Risk level
Risk Scenario #4						
<ol style="list-style-type: none"> 1. Agent acting on Type Certificate Holder's behalf 2. Agent does not transfer data—contractual problem 3. Type Certificate surrendered to TCCA with no data 4. Data submitted or available for ongoing airworthiness may be limited 	Human	Refer to Notes to Scenario #1 above.				

S2.2 What is the exposure interval?		10 Years				
S2.3 Develop risk scenarios Declaration		S2.4 Establish consequences		S2.5 Assess Probability, Severity & Exposure (provide explanations as necessary)		
Sequence of Events	Cause (N, E, T, H)	Consequences	Probability	Severity	Exposure	Risk level
Risk Scenario #1						
1. Applicant is relying on the Minister to demonstrate compliance but provides test plan and product.	Human	Refer to Notes below				
2. Minister takes on liability as a result of participating in showing conformity (i.e. flight test)						
Notes This new regulation transfers responsibility for compliance to the applicable basis of certification from the Minister to the applicant. There are no other elements of this new provision that are different than the current situation. Therefore, no new or unique risks are created.						

STEP 3: EVALUATING THE RISK ACTIVITY

S3.1 What is the activity that exposes Transport Canada to risk?

Writing and promulgating CAR 521

S3.2 Assess the possible cost and benefits to Transport Canada

Quantitative

Cost

Benefits

No Quantitative cost and benefits were assessed because the costs associated with the CAR 521 project would have been spent regardless although they would have been assigned to other work. The financial benefits of the project are negligible or difficult to identify. Regardless, the decision to proceed (or not) with CAR 521 is not driven by financial considerations

Qualitative

Cost

Benefits

Developing the guidance and training material is a huge task.

Simpler; 521 takes 22 documents and combines them into one

Minor impact on bilateral agreements

Harmonized with other national authorities, and may provide for further harmonization with associated guidance and training.

Some current guidance material may lapse because it will soon be replaced.

International recognition of the document

Delegation schedules will have to be updated; the scope of review is now much broader

Possibly, easier recognition of our products

May speed things up with Justice because this initiative will reduce some of the backlog there. This is consolidated into a single package, so there will be a single consultation required.

Delegation sections were updated years ahead of schedule

Simplified the maintenance of our regulatory structure.

S3.3 Summarize the costs/benefits in terms of impact

Everyone in the aircraft industry in Canada will benefit from this initiative. It is simpler, the maintenance of the regulation is easier, and there is the possibility for more recognition internationally. The costs to this initiative would, in most cases, have had to be absorbed regardless if the regulation advanced or not, because they would have had to be done anyway in support of CAR 511 and 513.

STEP 4: CONTROL THE RISK

S4.1 What are the possible methods for controlling risks identified in step 2?

Methods of Controlling Risk

1. Duration

Having identified the scenarios and consequences, the team determined that the level of risk associated with this portion of CAR 521 was unacceptable and chose to use the Decision Diamond to move directly to taking action on this Associated Risk.

The action taken will be to remove from the regulation the provision requiring the holder to surrender its proprietary data to the Minister while retaining the provision specifying the duration of certificate/approval. The Decision Maker, Martin Thieringer, is accountable for the implementation of this decision and will be revising the Notice of Proposed Rulemaking (NPA) accordingly.

2. Compliance with Obligations.

A number of risk scenarios associated with the new regulatory provisions on Compliance with Obligations were identified as having highest risk index (refer to table S2.3 Risk Scenarios # 4 and # 6). The consequences of these risks scenarios included both embarrassment to the Minister and applicants not being able to fulfill their continuing airworthiness obligations. These consequences were predominantly resulting from potential misunderstanding of the regulations by both TCCA personnel and applicants. The following steps are dealing with the identification of risk control measures to mitigate these high risks scenarios and resulting consequences.

Methods of Controlling Risk

1. Ensure good quality training
2. Provide checklist of items received from industry to developers of guidance material
3. Consult on guidance material
4. External check on scope of project
5. Identify upper management support for development of guidance material
6. Identify dedicated resources for development of guidance material
7. Prepare and test drive guidance material well in advance of regulations being put in place
8. Document all preventative actions
9. Get exterior specialized expertise (external company) and beta test the guidance material in a similar fashion to SMS
10. Focus on usability issues for guidance material.

Risk Control Options (**Group identified methods as appropriate into separate risk control options.**)

1. Develop guidance material and consult on it internally and externally (CARAC mailing list) as a prerequisite for developing training material and programs so that they are in place at Gazette I
2. Develop guidance material and consult internally as a prerequisite for developing training material and programs so that they are in place at Gazette I
3. Develop guidance material using a dedicated internal working group as a prerequisite for developing training materials and programs so that they are in place at Gazette I
4. Develop guidance, training and publicity material in parallel, using current approaches, testing both with prototype training so that refined materials and training are available at Gazette I

Process Note:

Upon completion of development of the options the team quickly reached consensus on the fourth option listed above as the best option to control risk. While it would have been possible to use the Decision Diamond approach at this point to move directly to Step 5: Take Action it was deemed more appropriate to move to Step 4.3 and provide additional information on the advantages of this particular Risk Control option. Three advantages were identified and no disadvantages, compared to the other options, were identified.

It is possible that, had the options not been identified first, the advantages listed below may have appeared as criteria in a Decision by Weights and scores approach. This is not unusual in this methodology.

Note: Table for step 4.2 has been omitted from this report for the reasons stated above.

S4.3 What is the preliminary choice (option with the highest weighting)

Option 4: Develop guidance, training and publicity material in parallel, using current approaches, testing both with prototype training so that refined materials and training are available at Gazette I

- Proven process
- Consistent with SMS, IR 21, CPR, PDA, Risk Assessment training
- Allow international participation

The team was unable to identify any disadvantages associated with this option when compared to the other options.

S4.4 What are the residual risks associated with this option and are they acceptable?

What are the residual risks associated with this option	What is the level of residual risk (P x S x E = Risk)	Is the level of risk acceptable Can it be managed? How?
People still may not read the material		All residual risks were deemed acceptable by the Risk assessment team. All of these were identified as ongoing situations within the organization with none of them posing enough of a threat so as to require additional management
People may not attend the training		
Internal resistance to change		
Required support from management is not substantive		

Note: In addition to the residual risks identified above, and associated with the recommended Risk control option, all those areas identified in step 2 and not assessed, remain as residual risk. There are two categories of residual risk that fit this description:

- Those areas of concern where some, but not all, of the risks had scenarios developed and assessed
- Those areas where no scenarios were developed because:
 - The initial evaluation indicted they were of low concern
 - The time constraints on the Risk Assessment

The latter of these two categories, where no scenarios were created, are listed below.

In the case where some, but not all, of the Associated Risks were developed into scenarios, the team believed that the scenarios which were developed in each category gave an adequate picture of the risks associated with that category.

S4.4 What are the residual risks associated with this option and are they acceptable?

<p>What are the residual risks associated with this option</p>	<p>What is the level of residual risk (P x S x E = Risk)</p>	<p>Is the level of risk acceptable Can it be managed? How?</p>
<p>LSTC to serialized STC</p> <p>There may be resistance from industry due to cost increase associated with higher data level.</p> <p>There may be an increased workload for TCCA because the higher standard for data packages will require more extensive review.</p> <p>Someone reading the CAR may not understand options on STC varieties; elimination of the term LSTC will be confused by industry.</p>		<p>All residual risks were deemed acceptable by the Risk assessment team.</p> <p>All of these were identified as ongoing situations within the organization with none of them posing enough of a threat so as to require additional management</p>
<p>Conformity</p> <p>There may be an unclear distinction between engineering conformity and product conformity (AM&M). There may be an overlap of responsibilities.</p> <p>Calibration standards not specified.</p> <p>The equipment may be inappropriate, or improperly calibrated.</p>		<p>All residual risks were deemed acceptable by the Risk assessment team.</p>
<p>RDA Applicability to a TSO item (roadmap)</p> <p>Holder Complies with Division O. Non-holder complies with Division M.</p>		<p>All residual risks were deemed acceptable by the Risk assessment team.</p>
<p>Continuation of ODA</p> <p>This is the obligation that every three years from their anniversary date the ODA holder request continuation of their authorization. It exists to provide the minister a basis to remove delegation if the individuals cannot be found.</p>		<p>All residual risks were deemed acceptable by the Risk assessment team.</p>

S4.4 What are the residual risks associated with this option and are they acceptable?

What are the residual risks associated with this option	What is the level of residual risk (P x S x E = Risk)	Is the level of risk acceptable Can it be managed? How?
<p>Classification of Change</p> <p>This is primarily about determining the procedures to be used when making a major or minor modification to a type design.</p>		<p>All residual risks were deemed acceptable by the Risk assessment team.</p>
<p>Part Marking</p> <p>This is primarily about pointing the holder of an approval or certificate to CAR Part II on how to mark a part.</p>		<p>All residual risks were deemed acceptable by the Risk assessment team.</p>
<p>Clarification Statement</p> <p>Roadmap...What your responsibility is depending on who you are.</p>		<p>All residual risks were deemed acceptable by the Risk assessment team.</p>

S4.5 Select final option/risk control measure

Develop guidance, training and publicity material in parallel, using current approaches, testing both with prototype training so that refined materials and training are available at Gazette.

STEP 5: TAKE ACTION

Process Note:

The team determined that it was too early for detailed planning of this particular Risk Control approach. They were able to identify Tasks and Accountabilities with approximate milestone dates.

Accountability for completion of this step in the Risk Management process lies with Gilles Morin for the first portion of the plan. Overall Accountability transfers from him to Crystal Cartney in early 2005 (Specific date TBD) as the initiative moves from Strategic to Operational considerations.

S5.1 Develop implementation plan, as required

Activity	Start date	Due date	Person accountable	Monitoring measure (milestone or deliverables)	Method of follow-up
Get ACMT to support the accepted intent at CARAC	2004 Q3		Martin		
Obtain written commitment from management team			Gilles/Martin		
Develop Checklist of guidance material			Crystal		
Generate FAQs			Gilles/Blake		
Categorize/prioritize existing documents (cancelled, revise, new)			Crystal		
List potential constraints			Gilles		
Identify regional contact as dedicated resource person			Crystal		
Conduct a brainstorming session on lessons learned from SMS, CPR, PDA, IR 21, Risk Management			Gilles		

S5.1 Develop implementation plan, as required					
Activity	Start date	Due date	Person accountable	Monitoring measure (milestone or deliverables)	Method of follow-up
Identify key issues needing new materials			Martin		
Identify foreign material that may be usable			Blake		
Identify work packages (WBS)			Gilles		
Develop workplan/timelines			Gilles		
Get AARBH and DOJ commitments on resources and timelines	2004 Q4		Gilles		
Get \$\$\$ in annual budget plan			Martin		
Prioritize documents			Crystal		
Identify support resources—translation, reviewing, publishing			Martin		
Assign primary contact to write/review document	2005 Q1		Crystal		
Write documents, translate, etc.			Crystal/Blake		
Find money for prototype training	2005 Q2		Martin		
Determine supplies and materials needed			Tony Bean		
Outline training package into chapters			Gilles		
Write each chapter			Gilles		

S5.1 Develop implementation plan, as required					
Activity	Start date	Due date	Person accountable	Monitoring measure (milestone or deliverables)	Method of follow-up
Translate training			Gilles		
Select trainers			Martin		
Train the trainers	2005 Q3		Martin		
Select training locations			Martin		
Invite training (prototype participants)			Gilles		
Request foreign participants for training and review			Gilles/Martin		
Select beta test candidates			Gilles/Martin		
Run prototype courses			Martin/Gilles		
Collate comments on training			Gilles		
Develop publicity material and tasks to support ease of use			Blake/Martin		
Revamp packages by Gazette I			Gilles/Crystal		
Get documents signed off			Crystal		
Create an implementation support team for post 521	2006 Q1		Gilles/Martin		

STEP 6: MONITOR IMPACT/FOLLOW UP

Process Note:

Step 6 will be completed following the further refinement of the plan in Step 5. Step 6 must be started as soon as dates, monitoring and follow up measures are identified for the early tasks listed in step 5. The initiation of Step 6 must not wait for the completion of Step 5.

S6.1, S6.2 & S6.3 What activities should be monitored, When should they be monitored and what method should be used to monitor?

Activity	When	By whom?	Method

S6.4 Assess the effectiveness of the risk control measures on the activities

What worked well	What concerns	Recommended corrective action

S6.5 Evaluate the effectiveness of the risk analysis process

What worked well	What concerns	Recommended corrective action
On site tracking and recording of discussions	Having missed internal participants in the initial identification	
Knowledge available in the team	Knowledge available... “La génie approche la folie”	
Facilitator keeping the team on track	The document (CAR 521) is not quite stable	
Small group size	The identification of the rules associated with a category on the posted flip chart sheet was a distraction...rather than focussing on the risks associated the team was distracted into examining the text of the regulation	
Being able to get together on short notice	Team members were in and out because of conflicting schedules.	
Layout of material on the walls		
Keeping on track		
The use of Post it notes to record and arrange information		

Appendix 1
**CIVIL AVIATION REGULATION ADVISORY COUNCIL
(CARAC)
PART V TECHNICAL COMMITTEE
Aircraft Certification**

**TERMS OF REFERENCE
For the Risk Assessment to CAR/CAR STD 521 Regulatory Initiative**

1. Background

During the recodification of the certification of aeronautical products process as part of the new *Canadian Aviation Regulations* (CAR), the content of the two original *Airworthiness Manual* (AWM) chapters 511 and 513, that were issued under the authority of the *Air Regulations*, was further divided into regulations and standards: Subpart 511 and 513 of the CARs, Chapters 511 and 513 of the AWM, thus requiring the use of four separate documents to have the complete vision of the Canadian certification process.

This situation proved to be cumbersome to use and difficult to understand for both Canadian and foreign aviation industry, and also foreign authorities. Over the years, it became evident that the Canadian certification process needed to be more user-friendly and harmonized with equivalent foreign certification process.

The recent introduction of the European Aviation Safety Agency Implementation Rule (IR-21) and the FAA initiatives to rewrite U.S. Federal Aviation Regulations (FAR) 21 made it even more obvious that Transport Canada regulations governing aircraft certification process needed to be improved and aligned with FAR 21 and the European IR-21.

Transport Canada Aircraft Certification, Regulatory Standards Division is currently preparing a proposal for a new CAR and CAR Standard 521, which is the culmination of a number of years of regulatory development activities in the area of aircraft certification. . The proposed regulations would be harmonized in its structure and, where possible, in its content with the certification process of the Federal Aviation Administration (FAA) and the European Aviation Safety Agency (EASA).

Before finalizing the Notices for Proposed Rulemaking in preparation for a Special 521 CARAC Part V Aircraft Certification Technical Committee scheduled for 24 November 2004, a risk assessment needs to be conducted to ensure the impact of the newly introduced aircraft certification requirements have been adequately considered and assessed.

2. Purpose

The objective of the risk assessment will be to identify those issues within the 521-Project regulatory initiative that require to be risk assessed and to proceed with the risk analysis for each of these issues individually.

3. Scope

The risk assessment team's tasks are to:

- Familiarize with the proposed 521-project initiative. A 521-overview presentation identifying the significant regulatory changes from the existing CAR/AWM 511 and 513 will be provided to the team members.
- Identify the issues of the 521-project that are subject to risk analysis given CARC direction that no risks assessment is required for those elements dealing with harmonization with the FAA and ICAO, and administrative amendments. Many of the 521-Project components will be based on the new EASA IR-21 that used as its basis the JAA JAR – 21 which was developed along the concepts of the FAA FAR 21. Therefore those components of CAR 521 that will be harmonized in intent and structure with both IR-21 and FAR-21 should not be subject to risk analysis. Also, any elements of the 521-project that are purely re-structuring the current regulatory requirements from CAR 511/513 and AWM 511/513 into CAR/STD 521 should not be subject to risk analysis as it is considered administrative amendments.
- Due to the potential complexity of each issue identified as requiring a risk assessment, a separate risk analysis should be conducted for each issue and the sum of these will constitute the overall risk assessment for the 521-Project. For each issue identified, the team will:
 - Identify the component of the hazards, risks scenarios and their evaluation in terms of probability, severity and exposure.
 - For risk scenarios identified as level two or higher (in accordance with risk index definition of Type 2A) the risk assessment should be continued to evaluate and control risks, and identify an action plan accordingly.

4. Approach

Given the uniqueness and complexity of the 521-project, the participants should use the risk assessment method they consider to be the most appropriate. Type 2A should be used as the basis but may be tailored to address specific issue being analyzed. For each issue, the risk analysis may be presented in the form of Issue Papers, which are commonly used in certification activities when required to identify problems, describe stakeholder positions and document final decision.

5. Team participation

The risk assessment should be limited to internal stakeholders for the following reasons:

- The 521-Project is the outcome of the CARAC 521 “Working Group on Harmonization of the Certification Process for Aeronautical Products and Parts” which included extensive participation from the Canadian aviation industry. The proposed 521 CAR and STD have taken into consideration all of the recommendations of this WG which were adopted at the CARAC Part V Aircraft Certification Technical Committee in May 2002.
- The Regulatory Standards Division of Aircraft Certification will conduct 521 sessions in four of the TCCA regional office areas to provide information on the new structure and contents of the proposed regulation and standard while serving as an informal forum for discussions to receive feedback from the participants.

Internal stakeholders should include as a minimum:

- One representative from each of the following Aircraft Certification divisions: Regulatory Standards, Projects and Delegation;
- One representative from Commercial and Business Aviation branch;
- One representative from Maintenance and Manufacturing branch; and
- One representative from System Safety branch to facilitate the risk assessment process.

6. Reporting and Timing

A final report should be prepared and ready for presentation and acceptance at CARC before the Special 521 CARAC Part V Technical Committee meeting scheduled for 24 November 2004.

Appendix 2:

Initial Sort Identifying Elements of CAR 521 which fall within the Terms of Reference of the Risk Assessment

Process Note:

The following table lists the individual regulations within CAR 521 and identifies which portions of that document must be assessed for risk because they are:

- Derived strictly from European IR's;
- Completely new (not derived from an existing Canadian document), and/or;
- Not harmonized with FAR's

The table provides five pieces of information. These are:

- **Reference:** This indicates the provision within CAR 521 being considered in the line.
- **Delta:** This indicates the change involved in, or source of, the particular regulation.
- **Comments:** This column is used to define the commonality between regulations that were linked for the purposes of Risk Assessment. If a regulation fell within the ToR of the project but could not be linked to other regulations, it is marked as unique. If the column is blank then that portion of CAR 521 did not fall within the ToR of the Risk Assessment.
- **Link:** This column names the category under which the particular regulation was grouped for the purposes of Risk Assessment.
- **Priority:** This column identifies the priority assigned in the initial sort to the category or unique regulation.

The table is sorted by Priority, followed by Link and then Reference. This table is also available from the members of the Risk Assessment team as an Excel file that can be sorted by any of the five columns or by criteria within the columns to parse the data in other useful ways.

Reference	Delta	Comments	Link	Priority
521.47(4)	IR	This is to ensure that the test specimen conforms to the proposed type design by performing an engineering conformity, and ensures that all equipment is properly calibrated to perform the tests; there is a need for the test specimen to be identified to the Minister for access and witnessing of the test.	Conformity	A-1
521.47(3)(a)	IR	This is to ensure that the test specimen conforms to the proposed type design by performing an engineering conformity, and ensures that all equipment is properly calibrated to perform the tests; there is a need for the test specimen to be identified to the Minister for access and witnessing of the test.	Conformity	A-1
521.47(2)	IR	This is to ensure that the test specimen conforms to the proposed type design by performing an engineering conformity, and ensures that all equipment is properly calibrated to perform the tests; there is a need for the test specimen to be identified to the Minister for access and witnessing of the test.	Conformity	A-1
521.47(2)(a)	IR	This is to ensure that the test specimen conforms to the proposed type design by performing an engineering conformity, and ensures that all equipment is properly calibrated to perform the tests; there is a need for the test specimen to be identified to the Minister for access and witnessing of the test.	Conformity	A-1
521.47(2)(a)(i)	IR	This is to ensure that the test specimen conforms to the proposed type design by performing an engineering conformity, and ensures that all equipment is properly calibrated to perform the tests; there is a need for the test specimen to be identified to the Minister for access and witnessing of the test.	Conformity	A-1
521.47(2)(a)(ii)	IR	This is to ensure that the test specimen conforms to the proposed type	Conformity	A-1

Reference	Delta	Comments	Link	Priority
		design by performing an engineering conformity, and ensures that all equipment is properly calibrated to perform the tests; there is a need for the test specimen to be identified to the Minister for access and witnessing of the test.		
521.47(2)(a)(iii)	IR	This is to ensure that the test specimen conforms to the proposed type design by performing an engineering conformity, and ensures that all equipment is properly calibrated to perform the tests; there is a need for the test specimen to be identified to the Minister for access and witnessing of the test.	Conformity	A-1
521.47(2)(b)	IR	This is to ensure that the test specimen conforms to the proposed type design by performing an engineering conformity, and ensures that all equipment is properly calibrated to perform the tests; there is a need for the test specimen to be identified to the Minister for access and witnessing of the test.	Conformity	A-1
Division O	New	This category is primarily about the obligations of a holder of a certificate upon releasing a certificate to the Minister, and surrendering the data so that the Minister may continue the airworthiness of the product.	Duration	A-1
521.213(2)(a)	New	This category is primarily about the obligations of a holder of a certificate upon releasing a certificate to the Minister, and surrendering the data so that the Minister may continue the airworthiness of the product.	Duration	A-1
521.59(2)(a)	New	This category is primarily about the obligations of a holder of a certificate upon releasing a certificate to the Minister, and surrendering the data so that the Minister may continue the airworthiness of the product.	Duration	A-1
521.611(2)(a)	New	This category is primarily about the obligations of a holder of a certificate upon releasing a certificate to the Minister, and surrendering	Duration	A-1

Reference	Delta	Comments	Link	Priority
		the data so that the Minister may continue the airworthiness of the product.		
521.761(2)(a)	New	This category is primarily about the obligations of a holder of a certificate upon releasing a certificate to the Minister, and surrendering the data so that the Minister may continue the airworthiness of the product.	Duration	A-1
Division O	New	This category is primarily about the certificate/approval holder's obligations and responsibilities to maintain the continued airworthiness of the product.	Obligations	A-1
521.171(2)	IR	This category is primarily about the certificate/approval holder's obligations and responsibilities to maintain the continued airworthiness of the product.	Obligations	A-1
521.171(1)	IR	This category is primarily about the certificate/approval holder's obligations and responsibilities to maintain the continued airworthiness of the product.	Obligations	A-1
521.217	IR	This category is primarily about the certificate/approval holder's obligations and responsibilities to maintain the continued airworthiness of the product.	Obligations	A-1
521.615	IR	This category is primarily about the certificate/approval holder's obligations and responsibilities to maintain the continued airworthiness of the product.	Obligations	A-1
521.63	IR	This category is primarily about the certificate/approval holder's obligations and responsibilities to maintain the continued airworthiness of the product.	Obligations	A-1
521.765	NPA 2001-022 and	This category is primarily about the certificate/approval holder's obligations and responsibilities to maintain the continued airworthiness	Obligations	A-1

Reference	Delta	Comments	Link	Priority
	IR	of the product.		
Division O	New	APU TSO is considered. 521.709	Unique	A-1
		LSTC to serialized STC	Unique	A-1
521.51	New	Flight test operations	Unique	A-1
521.53(2)	IR	This category is primarily about the applicant's written statement that they will comply with the continued airworthiness of the product.	Compliance with Obligations	A
521.57(2)	IR	This category is primarily about the applicant's written statement that they will comply with the continued airworthiness of the product.	Compliance with Obligations	A
521.169(1)(b)	IR	This category is primarily about the applicant's written statement that they will comply with the continued airworthiness of the product.	Compliance with Obligations	A
521.45(4)	IR	Declaration of compliance with certification basis	Declaration	A
521.163(1)(c)	IR	This is to specify the responsibility of an applicant to make a statement that they have shown compliance to the applicable certification basis.	Declaration	A
521.169(1)(a)	IR	This is to specify the responsibility of an applicant to make a statement that they have shown compliance to the applicable certification basis.	Declaration	A
521.53(1)	IR	This is to specify the responsibility of an applicant to make a statement that they have shown compliance to the applicable certification basis.	Declaration	A
521.57(1)	IR	This is to specify the responsibility of an applicant to make a statement that they have shown compliance to the applicable certification basis.	Declaration	A
521.155(2)	IR	This category is primarily about determining the procedures to be used when you are making a major or minor modification to a type design	Classification of change	B

Reference	Delta	Comments	Link	Priority
521.155(1)	IR	This category is primarily about determining the procedures to be used when you are making a major or minor modification to a type design	Classification of change	B
521.469(2)	New	This is the obligation that every three years from their anniversary date, an ODA holder requests continuation of their authorization; it exists to provide a basis for the minister to remove delegation if the individuals cannot be found.	Continuation of ODA	B
521.517(2)	New	This is the obligation that every three years from their anniversary date, an ODA holder requests continuation of their authorization; it exists to provide a basis for the minister to remove delegation if the individuals cannot be found.	Continuation of ODA	B
521.601(2)	New	RDA applicability, TSO road map	Unique	B
521.219	IR	This category is primarily about pointing the holder of an approval or a certificate to CAR part II, on how to mark a part.	Partmarking	C
521.617	IR	This category is primarily about pointing the holder of an approval or a certificate to CAR part II, on how to mark a part.	Partmarking	C
521.65	IR	This category is primarily about pointing the holder of an approval or a certificate to CAR part II, on how to mark a part.	Partmarking	C
521.205	IR	Change to a change (STC)--clarification statement	Unique	C
Division O	AWM 511.5 (old)	521.703		
521.515(6)	CAR 106			
521.659(6)	CAR 513.20, 21, 22 and AWM 513			

Reference	Delta	Comments	Link	Priority
521.659(5)	CAR 513.20, 21, 22 and AWM 513			
521.659(5)(a)	CAR 513.20, 21, 22 and AWM 513			
521.659(5)(b)	CAR 513.20, 21, 22 and AWM 513			
521.465(4)(f)	Reference is AWM 505.215(b)(2)			
521.45(3)	AWM 511.111(old)			
521.511(3)(m)	CAR 106			
521.653(3)	AWM 513.20, 513.21			
521.653(3)(a)	AWM 513.20, 513.21			
521.653(3)(b)	AWM 513.20, 513.21			
521.653(3)(c)	AWM 513.20, 513.21			
521.653(3)(d)	AWM 513.20, 513.21			
521.659(3)(a)	CAR 513.20, 21, 22 and AWM 513			

Reference	Delta	Comments	Link	Priority
521.659(3)(b)	CAR 513.20, 21, 22 and AWM 513			
521.71(3)	FAA order			
521.163(2)	will be deleted.			
521.201(2)	Links to CAR 513, not new			
521.45(2)	AWM 511.111(old)			
521.463(2)(o)	CAR 106			
521.477(2)(d)	Check against FAR requirements NPRM FAR 183.59			
521.525(2)(d)	NPRM FAR 183.59			
521.611(2)(b)	AWM 511.611(b)(old)			
521.613(2)	CAR 513.25			
521.613(2)(a)	CAR 513.25			
521.613(2)(b)	CAR 513.25			
521.653(2)	AWM 513.20, 513.21			

Reference	Delta	Comments	Link	Priority
521.661(2)	Section will be deleted			
521.753(2)(d)	Captured in ACSI 72			
521.761(2)(b)	AWM 511.611(b)(old)			
521.763(2)	NPA 2001-022			
521.763(2)(a)	NPA 2001-022			
521.763(2)(b)	NPA 2001-022			
521.07(1)	Not an IR reference			
521.09(1)(b)	This will be deleted			
521.09(1)(b)(i)	This will be deleted			
521.09(1)(b)(ii)	This will be deleted			
521.163(1)(a)	511.11(1)(b)			
521.203(1)	AWM 511.5 (old)	I		
521.45(1)	AWM 511.111(old)			
521.461(1)(b)(ii)	ACPL 72 was already consulted			

Reference	Delta	Comments	Link	Priority
521.603(1)	AWM 511.5 (old)			
521.613(1)	CAR 513.25			
521.653(1)	AWM 513.20, 513.21			
521.659(1)	CAR 513.20, 21, 22 and AWM 513			
521.661(1)	Section will be deleted			
521.753(1)(a)	AWM 511.5 (old)			
521.761(1)	AWM 511.611(a)(old)			
521.763(1)	NPA 2001-022			
521.05	FAR 21.303	Numbering is incorrect in this section		
521.05(d)	FAR 521.303(b)(4)	Numbering is incorrect in this section		
521.13	SMS is new to 511/513, but the information exists in CAR 106 through NPAs. We are enabling it.			
521.151	Lead in sentence			

Reference	Delta	Comments	Link	Priority
521.153	CAR 511.12			
521.203	AWM 511.5 (old)			
521.209	Points to CAR 513.11(1)(a)			
521.211	Points to CAR 513.11			
521.215	Reference is CAR 513.25 for all.			
521.603	AWM 511.5 (old)			
521.607	Points back to CAR 513.11(1)(a)			
521.609	Points back to CAR 513.11			
521.663	CAR 513.25			
521.665	AWM 511.611(a) and (b) (preCAR)			

Appendix 3
521 Risk Assessment
15, 27 July 2004

The following document provides an outline of the discussions and deliberations of the CAR 521 Risk Assessment team

Attendees:

Gilles Morin, Manager Domestic Regulations
Martin Thieringer, Manager Policy and Procedures
Bill Fossey, Manager National Audits
Crystal Cartney, Policy Officer
Al Lyon, Projects Manager
Jim Thomson, Flight Test
Cameron Frasier, RANA International, Consultant

Introduction

Gilles introduced the session and outlined the terms of reference of this initiative.

Industry has been extensively involved in the working group activities; all of their recommendations were considered in the rewrite. As well, because of the cross country tour to industry, there has been ample opportunity for them to comment. Industry voiced that there was very little concern over this initiative.

Commercial and Business Aviation declined to participate in this risk assessment.

Aircraft Certification has 3 representatives.

Maintenance and Manufacturing has one representative.

At the end, our objective is to provide a report to CARC. The schedule is very tight because there is a CARAC Technical committee during the week of November 22. To meet this deadline and send the packages to industry, the information must be submitted no later than September. Before that however, it has to go to translation so the report must be prepared by August 6. The CARC meets the end of September.

Background of the project

There is a corresponding FAR 21 and IR 21 to these regulations. We have attempted to harmonize wherever possible.

The type certification process is governed by four documents: CAR 511 and CAR 513; AWM 511 and 513. CAR 511 is the regulatory process for certifying products themselves; new products and new designs (originals). The certificate is commonly called a 'type certificate' (TC). AWM 511 is the corresponding standard. CAR 513 and AWM 513 are for changes to a type design (modifications to the type certified products). The certificates are called Supplemental Type Certificates (STC) or Limited Supplemental Type Certificates (LSTCs). We also have Repair Design Certificates (RDCs) governed under 513. The intent is to combine all of these documents into one document, the new CAR 521. There will be a corresponding standard but it will be small, and there will be a clear dividing line between them.

Martin and Gilles had gone to Europe to the EASA meeting, and liked the format of IR 21. As well, the FAA is rewriting their FAR and intend to harmonize as much as possible. They will now be going to Washington at their request, to present our new rule to them. We will be harmonizing between the three authorities as much as possible.

All of the design standards will be brought into 521. Currently, each enabled by a two or three line regulation (see CAR 523, 525, 527 etc). We are writing a clause that will enable the design standards and then remove the other regulations. This is similar to what the IR and FAR will do.

521 will also introduce a number of elements that are not promulgated but have been accepted by our CARC. The justice system is so slow that it takes several years for a change to a regulation to be promulgated. We have brought them all into 521. When that is done, we will cancel all the proposed Notice of proposed amendments (NPAs) that are currently in the queue.

Part Design Approval (PDA) for replacements parts is not in the CARs right now but the NPAs are in the queue. These will also be brought into the new rule.

Appliance Type Certificates will be replaced with Technical Standard Order (TSO). Currently we adopt FAA TSOs in a standard, but they will be adopted now through guidance material. As well, we are able to begin the process of having a Canadian TSO adopted in another country.

The Minister delegates his functions to industry through AWM 505. When the rewrite was in process, it was determined that AWM 505 had to be included in the new regulation. This was beyond the mandate of the 521 working group, but its inclusion was necessary. The model looks different, and is based on a new FAA proposal to change the delegation system. Their proposal is aligning with our system but we are adopting the wording. The FAA rule change came out in January (NPRM to FAR 183).

The risk assessment should cover two criterions: it does not harmonize with the FAA, or it is purely an administrative change.

The Regulation

The draft document contains all the source codes, so that it was clear how much material was new, and how much was from existing regulation. The source codes include the IR (European regulation), the FAR (American regulation), the CARs and the AWM, and Working Group recommendations.

The heart of this document is Division B and D. The processes for many of the other divisions are almost the same, and therefore point back to Division D.

Division O is not subject to risk assessment, because the introduction of this division was to harmonize with FAR 21 by eliminating the appliance type certificate and replacing it with something that is internationally recognized (which is the TSO design approval). However, where there were concerns in other areas, for example obligations and conformity statements, the parts were considered. APU TSO was also considered as a separate item.

Part Marking—Brian Whitehead said that 561 does not adequately address the responsibilities for part marking. Therefore, the provision for part marking cannot be removed from 521 at the moment. When 561 is incorporated in the future, it may be resolved at that time, and the proposed wording for 521 needs to be changed.

Priority Setting Criteria

- Imparts a significant change to the current regulations.
- Introduces or removes a burden on the applicant/holder.
- Introduces or removes a burden on the Minister.
- Changes costs to the applicant/holder.
- Changes the efficiency of the certification process.
- Provides a net benefit to the applicant/holder.

- Improves Minister's ability to fulfill responsibility re: Aeronautic Act.
- Involves international recognition.

Identification of Risk Scenarios

- **LSTC to serialized STC**
 - There may be resistance from industry due to cost increase associated with higher data level.
 - The recommendation is that the fees will not be higher, but there may be an increased cost to prepare the data package.
 - There may be an increased workload for TCCA because the higher standard for data packages will require more extensive review.
 - Someone reading the CAR may not understand options on STC varieties; elimination of the term LSTC will be confused by industry.
- **Flight Test Operations**
 - Industry may not be able to support this with sufficient flight test resources.
 - In most cases, they already have the manual, and if not, they will come to Flight Test to talk to them.
 - Applicability of requirement to large OEMs may be misunderstood.
 - Flight test says that we are quite specific in the regulation. This is not targeted to the 'big 3', because we are specific in who it applies to. Recommends changing probability to Low.
 - Flight test operations are a novel requirement in aircraft certification. It is not in FAR, or IR 21, and it is not harmonized. This may be an unfair burden or inadequately addressing a problem as a result of the novel requirement.
 - Flight test operations identified burden as low, concern for accuracy of regulation is low.
 - One of the objectives is to have it auditable. The large manufacturers already have it.
 - The small manufacturers will need to do some work, but it isn't a lot. The burden on the applicant is not onerous
 - This is addressing a safety plan...very much what SMS requires. The flight test ops in 521 could disappear, because it is captured in CAR 106. However, having it in 521 makes it visible.
 - Can we be challenged here?
 - 521.51 is basically about a manual, and procedures that are auditable.
 - If we take this approach with flight test operations, we could use the same approach for ODA procedures manual.
 - We have the element within an AMO to do Quality Assurance, but there are still elements to have manuals and maintenance processes etc. One hangs over all the rest.
 - Three options
 - This is the odd duck in 521; it does not belong here and we will kick it out in favour of SMS.

- Leave it alone and figure out how to do it.
 - Essentially leave it alone, but draw someone's attention to it in terms of SMS.
 - Putting it away hides it from SMS requirements.
 - Credibility of TC for lack of standard.
 - The manual would be approved to CAR standard 521.
 - Increased workload to TCCA.
 - Flight Test agrees. They will end up authoring manuals, but it is not an onerous task. It is just time consuming. We accept the manuals but we do not approve them.
 - [[scenario one]] Industry will seek expertise from Flight Test on how to write the manual.
 - Currently, they do not have documentation because there was no requirement to do so.
 - [[scenario two]] Applicant not sure if documentation is sufficient.
 - New requirement, no resources or expertise to write manual.
 - This was always dealt with informally, but an accident changed the process.
 - Consequences
 - Impact/delays on other activities within Flight Test—including assistance to the Regional Offices.
 - Delay approval of the client's documentation because of other activities in Flight Test.
 - May improve things down the road because the applicant will gain a better understanding of his role in Flight Test operations. (Disagree, this is a one time application, only approved in Headquarters).
 - The people who need the least help are the larger operators; the people who need the most are the smaller operators.
 - Flight test now involved in approval of operations manual, and there may be inconsistent approval of the ops manual because there may not be a standard.
 - Flight Test agrees that there will be some interpretation issues, regarding which regulations apply to which manufacturers. However, Flight Test also states that the severity should be low as well.
- **Division O**
 - Unique Canadian TSO may not be recognized internationally.
 - Unique Canadian TSO-DA may not be recognized internationally.
 - There may be a different level of involvement by TCCA versus FAA in the issue or acceptance of a TSO-DA. This may result in the perception of an unequal playing field.
 - There may be an inconsistent application of C-TSO-DA by TCCA and industry personnel.

- training and guidance will be made available.
 - APUs...there may be some question.
- Compliance with Obligations
 - Demonstrating a technical capability to show compliance is quite different than having a technical capability to put SMS in place. They may have technical capability but not an understanding of how to apply an AD. The entire safety culture of SMS and integrated reporting systems etc. does not necessarily include an understanding of how to do something. The potential Type certificate holder at the start of the process may not understand the obligation. Eligibility talks about technical capability, not management capability.
 - The applicant may refuse to comply.
 - The applicant may not fulfil continuing airworthiness responsibilities.
- Duration
 - The minister may not have sufficient resources or clear procedures to fulfil this responsibility.
 - There is no financial or legal consideration regarding the transfer of a certificate from the Minister, to whom it was surrendered, to a new holder. This would be a conflict of interest situation.
 - There may be situations where the STC information is not available for surrender to the Minister (assuming Minister is the holder).
 - Although the owner may surrender the property rights, he may not surrender all the data—and the Minister therefore may not be able to meet his obligations for continuing airworthiness.
 - Continuing airworthiness of the product may be in doubt.
 - The Minister may not be able to fulfil his ATIP responsibilities if the data is not surrendered.
- Conformity
 - There may be an unclear distinction between engineering conformity and product conformity (AM&M). There may be an overlap of responsibilities
 - Calibration standards not specified.
 - The equipment may be inappropriate, or improperly calibrated.
 - There is a risk that the Minister will get involved in disputes between companies over access to intellectual property.
 - There may not be personnel available to witness the test.
- Declaration
 - The applicant may refuse to comply.
 - The applicant may edit or transfer the statement in cases of Flight Test, because in that situation, the Minister may be taking on the partial role of the applicant. Minister may have to assume some liability for showing compliance for the Flight Test portion.
 - The applicant may make a false statement of compliance.

All items that were classified as B or C are so reliably low as to not require assessment. We were unable to identify anything that was significant.

Next Steps

Forward output to Cameron	Crystal	28 July 2004
Brief chiefs at management meeting	Gilles/Martin	29 July 2004
Write report	Cameron	03 August 2004
Review Report, write executive summary	Gilles/Martin	04 August 2004
Send report to CARC	Gilles	06 August 2004
CARC approval of report	Martin Eley, Gilles/ Martin	08 September 2004
Table risk assessment report at CARAC	Gilles	23 November 2004